Supreme Court U.S.
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No. 05-48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Federal law requires pharmaceutical companies to list, for every new drug, all patents that "could reasonably be asserted" against a generic version of the drug. To promote the prompt resolution of disputes concerning such patents — and thereby accelerate the introduction of generic drugs — Congress in 2003 specifically authorized generic drug companies to bring an action for a declaratory judgment that a listed patent was invalid or not infringed, 21 U.S.C. § 355(j)(5)(C)(i)(II), and directed federal courts to exercise subject matter jurisdiction over such actions "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). The questions presented are:

1. Whether the court below erred in holding, contrary to the rulings of other circuit courts and to this Court's decision in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), that a generic company can establish jurisdiction under Article III in declaratory judgment actions *only* by proving that it faces "a reasonable apprehension of imminent litigation" for patent infringement.

2. Whether the court below erred in holding that Congress intended to require such a reasonable apprehension of imminent litigation as a condition to the exercise of jurisdiction in declaratory judgment actions under 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5), even though that requirement is contrary to the plain meaning of these statutes and would preclude such actions in precisely the circumstances in which Congress intended to authorize them, *i.e.*, when, by delaying the commencement of infringement litigation, the patentee can effectively extend the term of pharmaceutical patents and delay competition from generic drugs.

LIST OF PARTIES

All parties in the proceedings below are listed in the caption to this petition.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parent corporations of petitioner, Teva Pharmaceuticals USA, Inc., are: Orvet UK Ltd., Teva Pharmaceuticals Europe, and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is a publicly held company that owns 10% or more of the petitioner's stock.

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OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit (App. 1a-36a) for which review by this Court is sought is reported at 395 F.3d 1324 (Fed. Cir. 2005). The order denying rehearing and rehearing en banc from that decision, together with the opinions dissenting from the denial of rehearing (App. 48a-66a), is reported at 405 F.3d 990 (Fed. Cir. 2005). The decision of the United States District Court for the District of Massachusetts reviewed by the Federal Circuit (App. 37a-47a) is set forth at 2003 U.S. Dist. LEXIS 21940 (D. Mass. Dec. 8, 2003).

JURISDICTION

The judgment of the Federal Circuit was entered on January 21, 2005. App 1a. A timely petition for rehearing and rehearing en banc was denied on April 4, 2005. App. 48a-50a. This Court has jurisdiction to review the judgment of the Federal Circuit under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, Art. III, section 2, clause 1 provides in pertinent part:

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority.

Section 505(j)(5)(C)(i)(II) of the Federal Food, Drug, and Cosmetic Act, as added by the Medicare, Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1101(a)(2)(C), 117 Stat. 2451 (2003), 21 U.S.C.A. § 355(j)(5)(C)(i)(II) (West Supp. 2005), reads in part:[1]

> **(C) Civil Action to obtain patent certainty**
>
> * * *
>
> If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the [abbreviated new drug] applicant referred to in such subclause may, in accordance with [28 U.S.C. § 2201], bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval ....

35 U.S.C.A. § 271(e)(5) (West Supp. 2005) (as added by Pub. L. No. 108-173, § 1101(d), 117 Stat. 2457 (2003)) provides:

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[1] The full text of 21 U.S.C. § 355(j)(5)(C) is set forth at App. 67a-70a.

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under [28 U.S.C. § 2201] for a declaratory judgment that such patent is invalid or not infringed.

INTRODUCTION

In 1984, Congress enacted the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetics Act[2] to accelerate the introduction of generic drugs in order to moderate the ever-increasing cost of prescription medication in the United States. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-74 (1990). A critical means for achieving this goal was to encourage the prompt resolution of disputes concerning the application of pharmaceutical patents to

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[2] Formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

proposed generic drug products *before* the launch of such drugs to eliminate patent uncertainty and to relieve generic companies of the need to risk potentially ruinous liability to determine whether their products infringe. To that end, Congress made the submission of an Abbreviated New Drug Application (an "ANDA") seeking regulatory approval to market a generic drug before the expiration of any such patent an "act of infringement" sufficient to support an immediate patent infringement lawsuit. 35 U.S.C. § 271(e)(2).

By 2003, Congress recognized that some pharmaceutical patentees refrained from bringing infringement lawsuits under § 271(e)(2) specifically to avoid resolving patent uncertainty and thereby to delay competition from generic drug companies. The ability of generic drug companies to forestall such delay by bringing declaratory judgment actions was in doubt because in non-ANDA cases the Federal Circuit had ruled that a plaintiff could seek a declaration of invalidity or non-infringement only by proving that it faced a reasonable apprehension of being sued for infringement. It was not at all clear that a generic company could make such a showing against a patentee that pursued a strategy of avoiding litigation. In response, Congress amended 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) specifically to direct district courts to hear declaratory judgment actions by generic drug companies "to the extent consistent with the Constitution."

However, in this case the Federal Circuit ruled *as a matter of constitutional law* that jurisdiction to hear such actions exists *only* where the generic company can prove that it faces imminent suit for patent infringement. This Court has never adopted such a rule, which is inconsistent with this

Court's Article III jurisprudence, and several other circuits have rejected it.

The Federal Circuit's ruling eviscerates the 2003 amendments by precluding generic companies from pursuing declaratory judgment actions in precisely the situations where Congress sought to make them available, *i.e.*, where a pharmaceutical patentee can effectively extend the life of its patent by *delaying* suit for patent infringement. Moreover, by grounding its ruling in the Constitution, the Federal Circuit effectively has tied Congress' hands. Only this Court's review can remedy this untenable situation.

STATEMENT OF THE CASE

Teva's Abbreviated New Drug Application

Petitioner, Teva Pharmaceuticals USA, Inc. ("Teva"), develops and sells generic drugs. In July 2002, Teva submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to sell a generic version of the antidepressant sertraline. Respondent, Pfizer, Inc. ("Pfizer") sells sertraline under the trade name Zoloft®. Zoloft is a very successful drug, generating annual sales revenue in the billions of dollars. App. 8a.

As required by the Hatch-Waxman Amendments, Pfizer had identified patents that could reasonably be asserted against a generic sertraline product. *See* 21 U.S.C. § 355(b)(1). Two of those patents are pertinent here: U.S. Patent No. 4,356,518 (the "compound patent") claims sertraline itself and expires in June 2006; U.S. Patent No. 5,248,699 (the "polymorph patent") claims a particular crystalline form or "polymorph" of sertraline, and expires in 2010. Pfizer listed these patents in the FDA's *Approved*

Drug Products with Therapeutic Equivalence Evaluations, a publication generally referred to as the "Orange Book."[3]

When Teva filed its ANDA for sertraline in 2002, it certified (i) that it would not market its generic sertraline product until the expiration of the compound patent, and (ii) that the polymorph patent was invalid and/or would not be infringed by Teva's generic sertraline product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III) and (IV). The first certification guaranteed that the FDA would not approve Teva's ANDA before the expiration of the compound patent four years later. 21 U.S.C. § 355(j)(5)(B)(ii). The second certification constituted an act of infringement of the polymorph patent sufficient to support federal subject matter jurisdiction over a patent infringement action against the ANDA applicant. 35 U.S.C. § 271(e)(2); *see Eli Lilly*, 496 U.S. at 678.

If Pfizer had sued Teva for infringing the polymorph patent within 45 days after receiving the second certification, the FDA would have been precluded from approving Teva's ANDA until either the court had ruled the patent invalid or not infringed or 30 months had elapsed, whichever occurred first. 21 U.S.C. § 355(j)(5)(B)(iii). Of course, since the FDA in any event would not approve Teva's ANDA until the expiration of the composition patent more than 30 months after the filing of Teva's ANDA, this automatic stay of FDA approval would have provided nothing of value to Pfizer.

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[3] The contents of the Orange Book are available online at http://www.fda.gov/cder/ob/default.htm.

Pfizer's Infringement Claim Against IVAX

Pfizer did not sue Teva within 45 days. Its forbearance, however, did not reflect indifference to competition to its blockbuster drug. Pfizer had earlier brought suit for infringing the polymorph patent against another generic drug company, IVAX Pharmaceuticals, Inc. ("IVAX"), that had filed an ANDA to market generic sertraline. That case settled[4] and the interplay between that settlement and federal pharmaceutical law explains Pfizer's decision not to bring an immediate infringement action against Teva.

Since IVAX was the first generic company to file an ANDA for approval of a generic sertraline product challenging the polymorph patent, it had an expectation of a lucrative 180 day "exclusivity" period during which no other generic sertraline product could be approved by the FDA. 21 U.S.C. § 355(j)(5)(B)(iv). However, like Teva, IVAX did not challenge the compound patent in its ANDA, and therefore was not in a position to enjoy its six months of "exclusivity" until the expiration of the compound patent in 2006. If any other generic company obtained a court decision that the polymorph patent was invalid or not infringed, the 180 day exclusivity period would commence, whether or not IVAX was able to launch its generic sertraline product. *See Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 780 (Fed. Cir. 2002). If such a court decision occurred more than 180 days before the expiration of the compound patent, IVAX would effectively lose its

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[4] Under the terms of the settlement, IVAX entered into a non-exclusive royalty-bearing license of the polymorph patent to commence upon the expiration of the composition patent. App. 9a.

exclusivity. In that situation, when the compound patent expired, Pfizer would face price competition, not only from IVAX (for which it would receive royalty payments), but also from other generic companies. It was, therefore, in Pfizer's interest to avoid, if possible, any litigation with another generic drug company that might have the effect of triggering IVAX's exclusivity before the expiration of the compound patent.

The District Court Decision

Teva sued Pfizer in January 2003 for a declaration that the polymorph patent was invalid and not infringed.[5] Teva sought to be in a position to launch its generic sertraline product immediately upon the expiration of the compound patent. However, avoiding the delay attributable to IVAX's exclusivity was not Teva's only concern. Teva faced exposure to significant infringement liability even if it delayed launching its product until after the compound patent expired *and* IVAX's exclusivity period had run. Teva sought to obtain patent certainty before launching, just as Congress had sought to encourage when it enacted the Hatch-Waxman Amendments in 1984. *See Eli Lilly*, 496 U.S. at 676.

Hoping to avoid any resolution of the patent issues (and thereby avoid any risk of triggering IVAX's exclusivity), Pfizer moved to dismiss Teva's action for want of subject matter jurisdiction, claiming that there was no "actual controversy." The district court granted the motion, ruling that Teva had not established that it faced a "reasonable apprehension ... that it will face an infringement

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[5] The bases for federal jurisdiction was 28 U.S.C. §§ 1331, 1338(a), 2201.

suit," as the court found to be required by Federal Circuit precedent. App. 43a-46a.

The Federal Circuit Panel Decision

On appeal to the Federal Circuit, Teva argued that legislation enacted in 2003 required the district court to hear Teva's declaratory judgment action. Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Amendments")[6] specifically authorized Teva to bring a "civil action to obtain patent certainty" against "the owner [of a patent listed in the Orange Book] or holder [of a New Drug Application for the drug associated with such listed patent] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the [ANDA] applicant seeks approval ...." 21 U.S.C. § 355(j)(5)(C)(i)(II). Congress further provided that district courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" in any such action. 35 U.S.C. § 271(e)(5). Teva argued that these amendments established subject matter jurisdiction so long as the underlying patent dispute was justiciable under Article III and that that its dispute with Pfizer was plainly justiciable under this Court's "case or controversy" jurisprudence.

A number of *amici curiae* also urged the Federal Circuit to reverse the dismissal of Teva's claim for declaratory relief. The Federal Trade Commission emphasized the "vital role" that declaratory judgment actions by generic companies play in bringing generic drugs quickly to market. The Commission argued that Teva had raised an "actual controversy" because the resolution of the patent

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[6] Pub. L. No. 108-173 (2003).

dispute between Teva and Pfizer affected the timing of FDA approval of Teva's ANDA and Teva therefore faced a redressable injury that potential infringers not subject to the pharmaceutical regulatory process do not face. Brief for *Amicus Curiae* Federal Trade Commission Supporting Appellant and Urging Reversal. AARP emphasized the importance of declaratory judgment actions in bringing generic drugs to market quickly to ameliorate the burdens of prescription drug costs on older Americans and on giving effect to Congress' direction that jurisdiction over such actions be exercised to the limits of Article III. Brief of AARP as *Amicus Curiae* in Support of Appellant.[7]

The Federal Circuit panel, in a 2-1 decision, rejected Teva's arguments and affirmed the dismissal. It ruled that Article III itself *requires* that a declaratory judgment plaintiff prove that the defendant's acts triggered a reasonable apprehension that the defendant will sue the plaintiff for patent infringement. App. 18a-21a. Moreover, the panel recast this "reasonable apprehension" test to require proof that the reasonably apprehended infringement suit be "imminent." App. 16a-17a.

The holding that the "reasonable apprehension of imminent suit" test is a constitutional rather than a prudential limitation on jurisdiction logically should have ended the matter. Nevertheless, the panel went on to rule that in enacting the Medicare Amendments, Congress intended to preserve that test as a jurisdictional limitation on declaratory

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[7] The Generic Pharmaceutical Association, a trade association of generic drug companies, also submitted an amicus brief in support of Teva's position.

judgment suits brought by ANDA applicants pursuant to those amendments. App. 21a-24a.

Judge Mayer dissented. He concluded that Article III does not require the "reasonable apprehension" test because the decisions of this Court, beginning with *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), establish that a "case or controversy" under Article III exists whenever the plaintiff has suffered injury in fact for which it seeks "specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts," App. 31a (quoting *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998) (quoting *Aetna*, 300 U.S. at 241)), and that Teva had presented such a case. Judge Mayer also concluded that Pfizer's act of listing the polymorph patent in the Orange Book, an act that represented to the world that that patent "likely precludes" a generic sertraline product, was sufficient to give rise to a reasonable apprehension of infringement litigation. App. 32a.

Denial of Rehearing and Rehearing En Banc

Teva petitioned for rehearing and rehearing en banc. Despite amicus submissions by the Federal Trade Commission and others urging rehearing, the Court denied the petition on April 4, 2005, with three judges dissenting. App. 48a-50a.

Judge Mayer did not supplement his panel dissent. The two other dissenters, Judges Gajarsa and Dyk, each filed dissenting opinions in which the other joined. Judge Gajarsa observed that this Court's decisions establish that Article III requires only a redressable injury in fact, traceable to defendant's conduct, *e.g.*, *Steel Co. v. Citizens for a Better*

Environment, 523 U.S. 83, 103-04 (1998), and that this constitutional "minimum" was satisfied here. App. 51a-57a.

Judge Dyk wrote that the Article III decisions of this Court "provided no support" for the Federal Circuit's view that only a "reasonable apprehension of imminent suit" can establish an actual controversy, and noted the inconsistency of the approach taken by the panel majority with rulings of other circuits. App. 60a-63a. He concluded that the Medicare Amendments were plain on their face in requiring district courts to hear declaratory judgment actions by ANDA applicants if Article III's minimum "case or controversy" standards were satisfied. App. 64a.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's ruling gravely undermines recent congressional efforts to accelerate the introduction of generic drugs and thereby ameliorate the staggering cost of prescription drugs in the United States. Both Congress and this Court have recognized that the prompt resolution of disputes involving the application of pharmaceutical patents to generic drugs is critical to the achievement of this goal. Congress amended the law in 2003 to authorize declaratory judgment actions by generic drug companies and thereby ensure that such companies would have the same opportunity to obtain prompt "patent certainty" that Congress gave pharmaceutical patentees in 1984.

The decision below effectively nullified those amendments. The court below not only denied declaratory relief in precisely the situations in which Congress sought to make such relief available, but also prevented Congress from ever providing such relief by grounding its ruling in the Constitution itself. It is difficult to imagine a more complete

frustration of congressional purpose in an area of vital importance to the nation's health care system. Accordingly, this case presents a "matter of special importance to the entire Nation," *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).

The Federal Circuit reached its decision by finding Article III requirements that this Court has never imposed and that go well beyond what this Court has repeatedly identified as the essential characteristics of a justiciable "case or controversy." There is no question but that there would be jurisdiction to resolve the dispute between Teva and Pfizer in an infringement action brought by Pfizer, and this Court has emphasized that the identity of the party that initiates litigation to resolve a justiciable controversy is "immaterial" to the Article III question. *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). The Federal Circuit's decision also conflicts with decisions from other circuits and denies access to declaratory relief in situations in which both the Medicare Amendments and the Declaratory Judgment Act were intended to apply.

If the decision below is allowed to stand, no district court in the country will entertain declaratory judgment actions as Congress provided in the Medicare Amendments. Appeals from dismissals of declaratory judgment actions in patent cases are heard exclusively by the Federal Circuit, and every district court is bound by Federal Circuit precedent in such cases. Hence, only review by this Court can correct the misreading of its precedents and the frustration of national health care policy caused by the decision below.

I. The Decision Below Gravely Undermines Congressional Efforts to Reduce the Cost of Prescription Drugs.

The price of prescription drugs has grown dramatically in recent years, creating enormous burdens for patients (particularly the elderly), for employers who provide prescription drug benefits for their employees, and for the taxpayers who fund Medicare, Medicaid and other public health care programs. National expenditures for prescription drugs have risen from $12 billion in 1980 to $40 billion in 1990 to more than $170 billion in 2003.[8]

Generic drugs play a critical role in moderating this explosive growth in the cost of prescription drugs. A study cited by the Federal Trade Commission in 2002 reported that average drug prices declined 20% within two years of generic drug entry into the market and that the savings increase with the number of generic competitors.[9]

This Court has recognized that the Hatch-Waxman Amendments sought to accelerate the introduction of generic drugs. *Eli Lilly*, 496 U.S. at 670. Generic entry was often delayed because pharmaceutical patents prevented generic drug companies from even commencing their development efforts until those patents expired. This delay, coupled with a

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[8] Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2003 (available at http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp.)

[9] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (2002) (available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.)

lengthy process of regulatory review, resulted in a *de facto* extension of the terms of pharmaceutical patents. *See id.*

The Hatch-Waxman Amendments addressed this problem in several ways. First, they required innovator companies to list in the Orange Book any patents that "could reasonably be asserted" against generic versions of the drugs to which they pertain. 21 U.S.C. § 355(b)(1). Second, they provided that the activities of companies to develop generic versions of patented products for purposes of seeking FDA approval would not constitute patent infringement. 35 U.S.C. § 271(e)(1). *See Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. ___, 125 S. Ct. 2372 (2005). Third, the Hatch-Waxman Amendments encouraged the resolution of patent disputes *before* generic companies launched their products (at risk of potentially ruinous liability) by (i) making the submission of an ANDA that seeks FDA approval before the expiration of an Orange Book patent (because the patent is invalid or not infringed) an act of infringement of such patent sufficient to support infringement litigation, and (ii) automatically delaying FDA approval of the generic drug by 30 months if the patentee commenced an infringement action within 45 days of receiving notice of this certification. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2).[10] This Court

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[10] The number of drugs as to which generic companies seek FDA approval before patent expiration is large and increasing. The FDA reports that since 1984 approximately 300 drugs have been the subject of ANDAs certifying that a patent said to cover the drug is invalid or not infringed, including more than 50 since March 2004. *See* http://www.fda.gov/cder/ogd/ppiv.htm. Since it is common for more than one generic drug company to file an ANDA with respect to a particular drug, these figures significantly understate the actual number of ANDAs filed containing such certifications.

recognized that without the ability to resolve infringement disputes promptly, the legislative scheme "will not work." *Eli Lilly*, 496 U.S. at 678.

By 2003, Congress recognized that the incentive of an automatic 30 month stay of FDA approval of a generic drug was often insufficient to prompt patentees to commence immediate infringement litigation against ANDA applicants that challenged their patents. As one supporter of the declaratory judgment provisions of the Medicare Amendments explained during the congressional debate over them:

> For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.
>
> .... Or when generic applicants are blocked by a first generic applicant's 180-day exclusivity,

> the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy) (App. 77a).[11] As lower courts had recognized, these delays could be avoided if generic companies could sue for a declaration of invalidity or non-infringement after the patentee failed to bring an infringement action within 45 days. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998); *Minnesota Mining*, 289 F.3d at 789-92 (Gajarsa, J., concurring).

The availability of this solution, however, was unclear in light of the Federal Circuit test for determining when a suit for a declaration of patent invalidity or non-infringement presented an "actual controversy." That test required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004) (quoting *BP Chems., Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)). Since filing an ANDA certifying that an Orange Book patent is invalid or not infringed constitutes infringement as a matter of law, it was the "reasonable apprehension of suit" requirement that raised questions whether a declaratory

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[11] The complete colloquy is set forth at App. 71a-81a.

judgment remedy would be available. *See Mova*, 140 F.3d at 1073.

In enacting Title XI of the Medicare Amendments — entitled "Access to Affordable Pharmaceuticals" — Congress sought to resolve this uncertainty by (i) expressly granting generic companies the right to seek a declaration of invalidity or non-infringement when the patentee does not bring suit within 45 days of receiving the generic company's certification, 21 U.S.C. § 355(j)(5)(C)(i)(II), and (ii) directing district courts to exercise jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5).

Congress plainly anticipated that this legislation would expand the ability of generic companies to bring declaratory judgment actions. ANDA applicants that could demonstrate a reasonable apprehension of suit could have brought declaratory judgment actions under existing Federal Circuit law without any further legislative authorization. Congress does not amend laws simply to preserve the legal status quo.[12] On the contrary, Congress expected that as a result of expanding declaratory judgment jurisdiction, patients would get quicker "access to affordable

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[12] Contrary to the Federal Circuit's conclusion, the Conference Committee Report does not reflect the intent of the conferees to apply the reasonable apprehension test whether or not the Constitution requires it. The report refers, consistent with the statutory language, to applying that test "to the extent required by Article III." *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) (App. 82a-83a). Nor does the Report reflect any conclusion by Congress that that test is constitutionally required.

pharmaceuticals" and dramatic cost savings would be achieved.[13]

The Federal Circuit decision completely frustrates that congressional purpose. The court not only ruled that the Constitution *always* required satisfaction of the "reasonable apprehension" test, but also reformulated the test to require a reasonable apprehension of *imminent* infringement litigation. As noted above, Congress provided that ANDA applicants could bring declaratory judgment actions specifically to address situations in which the owners of Orange Book patents had a financial incentive to *delay* the commencement of infringement litigation. Thus, *by imposing an "imminence" requirement, the Federal Circuit guaranteed that there would be no declaratory judgment remedy in precisely this situation in which Congress intended to make such a remedy available.*

The "imminence" requirement also undermines one of the principal goals of the Declaratory Judgment Act itself: to provide a remedy for a potential defendant that is unable to obtain a binding determination whether its product infringes a patent. The paradigm of this type of case involves what this Court, quoting Learned Hand, called a "scarecrow" patent, *i.e.*, a weak patent on which the patentee does not

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[13] According to estimates prepared for Congress by the Congressional Budget Office, enactment of Title XI of the Medicare Amendments would result in cost savings of $600 million through FY 2013 and (along with Title I of the Medicare Amendments) in $7.2 billion in increased revenues. Letter from Douglas Holtz-Eakin, Director Congressional Budget Office to Hon. William M. Thomas, Chairman, House Committee on Ways and Means (Nov. 20, 2003) (available at http://cbo.gov/ftpdocs/48xx/doc4808/11-20-MedicareLetter.pdf).

bring suit but that scares off the potential infringer and its customers. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993) (citing *Bresnick v. United States Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943) (L. Hand, J.)). In *Cardinal*, this Court noted that "[m]erely the desire to avoid the threat of a 'scarecrow' patent ... may ... be sufficient to establish jurisdiction under the Declaratory Judgment Act." *Id.* at 96.[14]

By definition, the victim of a "scarecrow" patent faces no likelihood of imminent infringement litigation. Yet the Federal Circuit's decision in this case would deny declaratory relief to the victims of such patents on constitutional grounds.

It is difficult to imagine a more complete undermining of important federal legislation than that brought about by the Federal Circuit's decision in this case. This Court should grant review to determine whether Article III genuinely requires such a result.

II. The Decision Below Purports to Resolve an Important Federal Question in a Manner that Conflicts with the Decisions of this Court and those of other Federal Circuit Courts.

The Medicare Amendments provide that district courts should exercise jurisdiction over declaratory judgment

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[14] Moreover, as Judge Hand said in another patent case, "[i]f a manufacturer fears that he will be charged to infringe, he can always inquire of the patentee, and if the answer is unsatisfactory, he can bring an action for a declaratory judgment. *The time has now passed when a patentee may sit by and refuse to show his hand.*" *Clair v. Kastar*, 148 F.2d 644, 646 (2d Cir. 1945) (emphasis added).

actions brought by generic drug companies in the circumstances presented here unless it is unconstitutional to do so. 35 U.S.C. § 271(e)(5). This Court has recognized Congress' authority to preclude the application of any merely prudential limitation on the subject matter jurisdiction of federal courts. *E.g.*, *Bennett v. Spear*, 520 U.S. 154, 162 (1997); *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

This Court has ruled repeatedly that Article III's "irreducible constitutional minimum" is that the plaintiff "demonstrate that he has suffered 'injury in fact,' that the injury is 'fairly traceable' to the actions of the defendant, and that the injury will likely be redressed by a favorable decision." *E.g.*, *Bennett*, 520 U.S. at 162 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). In no case discussing this constitutional minimum has this Court required a "reasonable apprehension of imminent litigation."

In particular, the Court imposed no such requirement in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), which upheld the constitutionality of the Declaratory Judgment Act against Article III challenge and established the framework for analyzing the applicability of Article III to declaratory judgment actions. In the words of Chief Justice Hughes, to fall within the "judicial Power" of Article III, the declaratory plaintiff's claim "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of

facts." *Id.* at 241.[15] The insurance company plaintiff in *Aetna* sought a declaration of non-coverage and there is no hint in the Court's opinion that the insurer faced any threat of imminent litigation. The harm that the insurer invoked to justify declaratory relief was the prejudice to its ability to prove non-coverage through the death or disappearance of witnesses. *Id.* at 239.[16] *See also Asarco, Inc. v. Kadish*, 490 U.S. 605, 619 (1989) (articulating requirement for "case or controversy" in terms of the adversity of the parties and the existence of valuable legal rights that will be affected "to a specific and substantial degree by the decision of the question of law").

The Federal Circuit never attempted to ground its reasonable apprehension requirement in the Article III decisions of this Court. Rather, it read its own prior decisions as setting forth constitutional requirements, even though the Article III question was not squarely presented in any of those cases. This case is the first patent case reviewed by the Federal Circuit where Congress has directed the exercise of subject matter jurisdiction to the constitutional

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[15] This standard is clearly satisfied here. Teva seeks a judicial determination whether the specific pharmaceutical product described in exacting detail in its ANDA will infringe Pfizer's patent and whether the patent itself is valid. It has committed a statutory act of infringing that patent. There is nothing hypothetical about Teva's claim.

[16] In *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270 (1941), this Court extended the *Aetna* holding to permit an insurer to sue the party injured by its insured for a declaration of non-coverage. Although the injured party would have had the right to sue the insurer after obtaining a judgment against the insured, the injured party had not obtained such a judgment when the insurer brought its declaratory judgment action. Plainly, the insurer faced no *imminent* risk of coverage litigation.

limit. Accordingly, prior Federal Circuit precedent should not have precluded consideration of general principles of justiciability under Article III.

Teva plainly satisfied the "irreducible constitutional minimum" of injury, traceability and redressability, as the dissenting judges all recognized. Unless Teva can obtain a judicial determination whether its generic version of Zoloft infringes Pfizer's patent, it cannot trigger IVAX's exclusivity and thereby avoid delaying the launch of its generic product until at least six months after the composition patent expires. Nor can it avoid the risk of ruinous liability if it launches before such a determination. Those injuries are traceable to Pfizer's listing the polymorph patent in the Orange Book and they will be redressed by litigating the validity and infringement of that patent.[17]

Moreover, a concrete dispute exists between Teva and Pfizer because Teva has already committed a statutory act of infringement that gives rise to a dispute that is unquestionably justiciable at Pfizer's behest. "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case." *Maryland Cas.*, 312 U.S. at 273. Since an infringement suit brought by Pfizer within 45 days of Teva's certification with respect to the polymorph patent would have been justiciable, Teva's

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[17] The Federal Circuit minimized this injury as a mere "competitive disadvantage." App 26a. But a "competitive disadvantage" is precisely what the victims of "scarecrow" patents suffer, and this Court indicated in *Cardinal Chem.* that such harm may support a declaratory judgment action. Competitive injury is certainly "injury in fact" for Article III purposes. *See Ass'n of Data Processing Serv. Orgs. v. Camp*, 397 U.S. 150, 151-52 (1970).

declaratory judgment action presenting the identical issues in a case involving the identical parties is justiciable as well. That Pfizer was not about to sue Teva does not affect this conclusion.

The "reasonable apprehension of imminent litigation" requirement is not only foreign to this Court's Article III jurisprudence; it also conflicts with the Article III decisions of other circuits. In *Sallen v. Corinthians Licenciamentos Ltda,* 273 F.3d 14 (1st Cir. 2001), the First Circuit expressly rejected the proposition that Article III requires a party seeking a declaration of his right to use the defendant's trademark in its internet domain name to demonstrate a reasonable likelihood that it will be sued for trademark infringement. The court noted that where an actual concrete controversy exists between the parties, it was unnecessary to prove that the defendant was reasonably likely to commence an infringement action. *Id.* at 25-26.

Similarly, in a recent unpublished decision, the Sixth Circuit also rejected the proposition that a reasonable apprehension of suit is categorically required to satisfy Article III. *Sankyo Corp. v. Nakamura Trading Corp.*, 2005 U.S. App. LEXIS 4339, at *9-*11 (6th Cir. Mar. 15, 2005). The court relied instead on the principles of justiciability set forth in the *Aetna Life* decision and the three-part test of injury, traceability and redressability.

Other circuits have formulated the "actual controversy" requirement for declaratory judgments in terms of whether the plaintiff faces a reasonable apprehension of future liability, not of imminent litigation. Indeed, that was the approach taken in patent decisions by other circuits before the establishment of the Federal Circuit. For example, in *Societe de Conditionnement en Aluminium v. Hunter*

Engineering Co., 655 F.2d 938 (9th Cir. 1981), the patentee specifically disclaimed any threat of infringement litigation, although, like Pfizer, it "refused to forbear from any future threats or litigation concerning" its patents. *Id.* at 941. Nonetheless, the court found an actual controversy sufficient to sustain a suit for a declaration of invalidity. Emphasizing that the constitutional standard was established by *Aetna*'s requirement of a "real and substantial controversy admitting of specific relief through a decree of a conclusive character," the court of appeals rejected any requirement of a threat of litigation. The critical fact was that the plaintiff had actually commenced arguably infringing activity as to which the patent presented a "Damoclean threat." *Id.* at 945.[18]

Because the Federal Circuit has departed from this Court's settled Article III principles and has announced a jurisdictional rule that conflicts with the decisions of other circuits, this Court should grant review.

III. The Decision Below will Impose an Unjustified and Unprecedented Limitation on Subject Matter Jurisdiction in Patent Cases throughout the Country that Congress will be Unable to Remedy.

The untenable situation created by the Federal Circuit's decision can only be remedied by this Court. The

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[18] *See also Starter Corp. v. Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996) (*per curiam*) (trademark case; "reasonable apprehension of liability"); *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555-56 (9th Cir. 1989) (copyright case; "reasonable apprehension ... of liability"); *Dewey & Alma Chem. Co. v. American Anode, Inc.*, 137 F.2d 68, 71 (3d Cir. 1943) (patent case; public notice by the patentee that certain practices constitute patent infringement supports declaratory judgment action).

Federal Circuit has exclusive jurisdiction over appeals in patent cases. 28 U.S.C. § 1295(a). Future litigants may seek en banc review from the Federal Circuit, but the refusal of that court to grant such review in this case, notwithstanding the cogency of the dissenting opinions and the urgings of the Federal Trade Commission, AARP and others as *amici curiae* in this case, lead one to infer that a majority of the Federal Circuit is committed to support the views of the panel in this case.

Moreover, by grounding its decision in the Constitution itself, the Federal Circuit has effectively prevented Congress from ever creating a declaratory judgment remedy in the circumstances presented here. Although the Federal Circuit inferred — incorrectly — that Congress intended to preserve the "reasonable apprehension" test, in the end Congress' intent does not matter if, as the Federal Circuit held, the test is constitutionally required. For this reason as well, the Court should grant review.

CONCLUSION

The Federal Circuit has grafted onto Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that this Court has never articulated and that other circuit courts have rejected outright.

For the reasons set forth herein, this Court should grant the petition for certiorari.

July 5, 2005

Respectfully submitted,

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APPENDIX

Appendix A — Opinion of the United States Court of Appeals for the Federal Circuit Filed January 21, 2005

United States Court of Appeals for the Federal Circuit

04-1186

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee.

DECIDED: January 21, 2005

Before MAYER*, CLEVENGER, and SCHALL, Circuit Judges.

Opinion for the Court filed by Circuit Judge SCHALL. Dissenting opinion filed by Circuit Judge MAYER.

SCHALL, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") is a manufacturer of generic pharmaceuticals. In July of 2002, it filed an Abbreviated New Drug Application ("ANDA") pursuant to the provisions of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. In its ANDA, Teva sought the approval of the Food and Drug

* Judge Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

Administration ("FDA") to market its generic version of the drug sertraline hydrochloride. Sertraline hydrochloride is sold under the trade name Zoloft® by Pfizer, Inc. ("Pfizer"). Pfizer holds two patents relating to Zoloft®: U.S. Patent No. 4,536,518 (the '518 patent") and U.S. Patent No. 5,248,699 (the '699 patent").

When Teva filed its ANDA, it also filed what is called in Hatch-Waxman parlance a "paragraph III certification." In that certification, Teva stated that it would not market its generic drug until the '518 patent expires. Simultaneously, Teva filed a Hatch-Waxman "paragraph IV certification." In that certification, Teva stated that its generic drug did not infringe the '699 patent or, alternatively, that the '699 patent is invalid. The '699 patent expires after the '518 patent. Pursuant to the provisions of the Hatch-Waxman Amendments, Pfizer had forty-five days from the date it received notice of Teva's paragraph IV certification to sue Teva for infringement of the '699 patent, and during that period the statute barred Teva from filing a declaratory judgment action against Pfizer based upon its ANDA.

On January 24, 2003, after Pfizer failed to sue Teva within the forty-five-day period following Pfizer's receipt of notice of the paragraph IV certification, Teva filed a declaratory judgment action against Pfizer in the United States District Court for the District of Massachusetts. In its suit, Teva sought a determination that its generic drug did not infringe Pfizer's '699 patent or that the claims of the '699 patent were invalid. On December 8, 2003, the district court dismissed Teva's suit for lack of jurisdiction. It did so on the ground that Teva had failed to establish that an actual controversy existed between it and Pfizer, as required under

the Declaratory Judgment Act, 28 U.S.C. § 2201(a).[1] *Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. 03- CV-10167-RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

Teva now appeals the decision of the district court, claiming that the court erred as a matter of law in holding that there was no actual controversy between it and Pfizer. The court determined that Teva failed to show that Pfizer had taken actions giving rise to a reasonable apprehension on its part that Pfizer would sue it for infringement of the '699 patent. Having considered the arguments of the parties and several amici,[2] we see no error in the district court's ruling that Teva failed to establish that an actual controversy existed between it and Pfizer. We therefore affirm.

BACKGROUND

I.

A. *The Hatch-Waxman Amendments*

The Hatch-Waxman Amendments were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282). In the Amendments, Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2)

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[1] Unless otherwise indicated, all statutory references are to the 2003 version of the United States Code.

[2] Amicus Curiae Ivax Pharmaceuticals, Inc. submitted a brief in support of Pfizer urging affirmance. Amici Curiae the Federal Trade Commission, the Generic Pharmaceutical Association, and AARP submitted briefs in support of Teva urging reversal.

enabling competitors to bring low-cost, generic copies of those drugs to market. *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

In order to speed up the approval process for generic drugs, the Amendments provide that a generic drug manufacturer may submit an ANDA for approval by the FDA, rather than a full New Drug Application ("NDA"). The ANDA may rely on the safety and efficacy studies previously submitted as part of the NDA by demonstrating the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A). Under 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to engage in otherwise infringing acts necessary to prepare an ANDA. However, section 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. 35 U.S.C. § 271(e)(2).

The Hatch-Waxman Amendments provide that NDA-holders must notify the FDA of all patents that "claim[ ] the drug for which the [NDA] applicant submitted the application ... and with respect to which a claim of patent infringement could reasonably be asserted ...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). As part of the approval process, an ANDA applicant must make one of four certifications with respect to each patent listed in the Orange Book that claims the drug for which it is seeking approval: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is

submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.

Upon filing a paragraph IV certification as part of an ANDA, an applicant must give notice to the patentee and the NDA holder. The notice must include a detailed statement of the factual and legal bases for the opinion of the applicant that the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B)(i). If the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires. 21 U.S.C. § 355(j)(5)(B)(iii). During this forty-five day period, the ANDA applicant is barred from filing a declaratory judgment action with respect to the patent at issue. *Id.* If no infringement action is filed during this forty-five day period, the FDA may approve the ANDA. *Id.*

The first ANDA applicant to file a paragraph IV certification enjoys a 180-day period of generic marketing exclusivity, during which the FDA may not approve a subsequent generic applicant's ANDA for the same drug product. 21 U.S.C. § 355(j)(5)(B)(iv). This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to "design around" patents to find alternative, non-infringing forms of patented drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 57 (July 2002). The 180-day exclusivity period typically begins on the date of the first commercial marketing of the drug by the first applicant. 21 U.S.C. § 355(j)(5)(B)(iv). The original Hatch-Waxman Amendments provided that the commencement of the 180-day exclusivity period could also be triggered by "the date of

a decision of a court ... holding the patent which is the subject of the certification to be invalid or not infringed."[3] *Id.*

B. *The 2003 Medicare Amendments*

Congress recently enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. The Act was signed into law on December 8, 2003. Title XI of the Act, entitled "Access to Affordable Pharmaceuticals," makes numerous changes in the Hatch-Waxman Amendments ("Medicare Amendments"). Among the changes is a provision for a "civil action to obtain patent certainty." 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). Pursuant to that provision, if the patentee or NDA-holder does not bring an infringement action within forty-five days after receiving notice of a paragraph IV certification, the ANDA applicant may bring a civil action for a declaratory judgment that the patent at issue is invalid or will not be infringed by the drug for which the applicant seeks approval. *Id.* In exchange, the ANDA applicant must make an offer of confidential access to its ANDA application so that the patentee or the NDA-holder can evaluate possible infringement. *Id.* The Medicare Amendments also provide that when the above circumstances are met, "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

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[3] As discussed in Part I.B., *infra,* in 2003 Congress enacted a more complex set of provisions relating to the 180-day exclusivity period. However, these new provisions do not apply in this case.

Congress also addressed the statutory scheme surrounding the 180-day market exclusivity period. Congress replaced the traditional court decision "trigger" with a more complex set of 180-day provisions. *See* 21 U.S.C. § 355(j)(5)(D) (Supp. 2004). However, the Medicare Amendments provide that these new forfeiture provisions are effective only with respect to those applications filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003. Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b), 117 Stat. at 2460. Thus, the new forfeiture provisions do not apply in this case.

II.

A. *The '518 and '699 Patents*

Pfizer's '518 patent, which expires on June 30, 2006, is directed to the chemical compound sertraline hydrochloride, which is useful for the treatment of mental depression and anxiety disorders.[4] Sertraline hydrochloride operates by interacting with serotonin, a chemical messenger that participates in the transmission of nerve impulses in the brain. Sertraline hydrochloride works to selectively block the uptake of serotonin by synaptic cells, thus reducing its re-entry into nerve cells and allowing serotonin levels between nerve cells in the brain to build up. Pfizer's '699 patent, which expires on September 28, 2010, is directed to a novel crystalline form of sertraline hydrochloride and to a method

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[4] The '518 patent was due to expire on December 30, 2005. However, the district court opinion explains that the FDA granted Pfizer a six-month pediatric exclusivity extension for the drug, pursuant to 21 U.S.C. § 355a, making June 30, 2006 the effective expiration date of the patent.

for preparing it.[5] The commercial embodiment of the '518 and '699 patents is the drug Zoloft®, a hugely successful drug which has been approved by the FDA for treatment of mood and anxiety disorders. According to Pfizer's Annual Report, Zoloft® generated revenues for the company in excess of $2 billion in 2002.

B. *Ivax Pharmaceuticals USA, Inc.'s ANDA filing relating to generic sertraline hydrochloride tablets*

Ivax Pharmaceuticals USA, Inc. ("Ivax") is a manufacturer of generic pharmaceuticals. In 1999, Ivax, then known as Zenith Goldline Pharmaceuticals, Inc., submitted an ANDA to the FDA for its generic version of sertraline hydrochloride. Since Pfizer had listed both the '518 and '699 patents in the Orange Book in connection with its NDA for Zoloft® tablets, Ivax was required to file a certification with respect to each patent as part of its ANDA. Ivax filed a paragraph III certification as to the '518 patent, stating that it was not seeking to market its generic version of sertraline hydrochloride prior to the expiration of the patent. Simultaneously, Ivax filed a paragraph IV certification as to the '699 patent, stating that its generic drug did not infringe the '699 patent, or alternatively, that the '699 patent was invalid.

Within forty-five days of its receipt of notice of Ivax's paragraph IV certification, Pfizer filed suit against Ivax for infringement of the '699 patent in the United States District Court for the District of New Jersey. *Pfizer, Inc. v.*

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[5] The district court's opinion recites that the '699 patent expires on September 29, 2010. We note that the electronic version of the Orange Book located on the FDA's website indicates that the '699 patent also was granted a six-month pediatric exclusivity extension.

Ivax Pharms. Inc., Nos. 00-408, 01-6007 (D.N.J. Jan. 1, 2000). In 2002, Pfizer and Ivax entered into a settlement agreement whereby Pfizer agreed to grant Ivax a royalty-bearing license on the '699 patent until its expiration in 2010. As a consequence of the agreement, Ivax is in a position to begin marketing its generic version of Zoloft® immediately upon expiration of the '518 patent on June 30, 2006.

As the first-filer of an ANDA for the generic version of Zoloft®, Ivax is entitled, under 21 U.S.C. § 355(j)(5)(B)(iv), to a 180-day generic market exclusivity period. This 180-day period will be triggered by the earlier of: (1) the first date of commercial marketing by the first generic applicant or (2) a "decision of a court ... holding the patent which is the subject of the [paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II).

C. *Teva's ANDA filing relating to generic sertraline hydrochloride tablets*

As noted, in July of 2002, Teva submitted an ANDA to the FDA for its generic version of Zoloft®. Like Ivax, Teva filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. Pfizer elected not to file suit against Teva for infringement of the '699 patent within the forty-five days following receipt of notice of Teva's paragraph IV certification, and to date no such suit has been filed.

D. *Teva's declaratory judgment action*

On January 24, 2003, Teva filed a declaratory judgment action in the United States District Court for the District of Massachusetts, seeking a declaration that its

generic version of Zoloft® does not infringe the '699 patent and a declaration that the '699 patent is invalid. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of the absence of an actual controversy, as required by Article III of the Constitution. On December 8, 2003, the court granted Pfizer's motion to dismiss.

In addressing Pfizer's motion, the district court applied the two-part test formulated by this court to determine whether an actual controversy exists in a patent infringement suit. Under that test, there must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity. *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). The district court determined that Teva had satisfied the second prong of the test by filing its ANDA for generic sertraline hydrochloride. However, the court concluded that Teva had failed to satisfy the "reasonable apprehension" prong of the test.

Before the district court, Teva argued that Pfizer had created a reasonable apprehension of suit based upon the following considerations: (1) Pfizer had listed the '699 patent in the Orange Book; (2) Pfizer had refused to grant Teva a covenant not to sue; (3) Pfizer had aggressively asserted its patent rights against alleged infringers of other patents; (4) Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride; and (5) it was in Pfizer's self-interest to leave a "cloud of litigation" hanging over Teva.

With respect to the final consideration, Teva argued that Pfizer's settlement with Ivax gave Pfizer a vested interest in seeing Ivax preserve its 180-day exclusivity period.

The district court rejected Teva's contentions. First, the court noted that a blanket inference that, by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer would virtually eliminate the "reasonable apprehension" prong of the two-part test. Second, the court stated that there is nothing in the Federal Food, Drug, and Cosmetic Act that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Third, the court found that Teva's subjective belief that it would be sued because Pfizer sued Ivax does not amount to an explicit threat indicating the imminence of suit. Finally, the court reasoned that, if anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospect of an immediate lawsuit against Teva even less likely.

Teva timely appealed the district court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2000).

ANALYSIS

I.

Our starting point is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), the statute under which Teva filed its suit. The Act provides in relevant part as follows:

> In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading,

> may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

The Act, which parallels Article III of the Constitution, "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Generally, the presence of an "actual controversy," within the meaning of the Act, depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has substantial discretion to decline that jurisdiction. *Id.; see also Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995) (reaffirming that since its inception, "the Declaratory Judgment Act has been understood to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants"). As we summarized in *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991): "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."[6]

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[6] Because the district court dismissed Teva's suit for lack of jurisdiction, it did not reach the stage of exercising its jurisdiction to determine whether to entertain the suit.

This court has developed a two-part inquiry to determine whether there is an actual controversy in a suit requesting a declaration of patent non-infringement or invalidity. *EMC Corp.*, 89 F.3d at 811. The inquiry focuses on the conduct of both the patentee and the potential infringer. *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1380 (Fed. Cir. 2004). There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity. *Id.*; *Amana Refrigeration*, 172 F.3d at 855; *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

Teva contends on appeal that the district court erred in ruling that it had failed to demonstrate the existence of an actual controversy between it and Pfizer under our two-part test. Teva argues that it had reasonable, objective grounds to fear that Pfizer would bring an action for infringement of the '699 patent. Teva also argues that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the two-part test.

Our task is thus two-fold. First, we must determine whether the district court erred in holding that Teva failed to establish an actual controversy under Article III because it did not demonstrate that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent. Second, if we determine that the district court did not err in applying the law as it existed when it granted Pfizer's motion to dismiss, we must determine whether, as Teva argues, the effect of the Medicare Amendments was to establish jurisdiction in the district court over Teva's

declaratory judgment action. It is to the former question that we turn first.

II.

The district court's dismissal of Teva's declaratory judgment action for lack of jurisdiction presents a question of law that we review without deference. *Gen-Probe*, 359 F.3d at 1379. The parties agree that the second prong (present infringing activity) of our two-part test was met by the filing of Teva's paragraph IV certification with respect to the '699 patent. The case thus turns on the first prong (reasonable apprehension of suit). Teva argues that the district court erred when it determined that Pfizer had not created a reasonable apprehension that it would bring suit against Teva for infringement of the '699 patent.

As it did in the district court, Teva places primary significance on the fact that Pfizer listed the '699 patent in the Orange Book, thereby representing that the patent "could reasonably be asserted" against any generic sertraline product. Teva takes the position that the requirements of the reasonable apprehension prong of the two-part test are satisfied in virtually every case in which: (1) the NDA applicant has listed a patent in the Orange Book; (2) a generic manufacturer has submitted an ANDA which includes a paragraph IV certification for a drug covered by that patent; and (3) the NDA-holder or patentee has not brought an infringement suit within 45-days of receiving notice of the paragraph IV certification. Teva asserts that the only way a patentee in Pfizer's situation can defeat jurisdiction over an ANDA filer's declaratory judgment action is by affirmatively representing that it will not sue the filer.

Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced. The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "*could* be reasonably asserted ...." 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however. *See Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) ("More is needed than knowledge or notice of an adversely held patent.... The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff." (citations omitted)). We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

In support of its contention that it was under a reasonable apprehension that Pfizer would sue it for infringement of the '699 patent, Teva also points to Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue. We have stated that, "[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)). Although relevant to the analysis, neither of the factors upon which Teva relies is

dispositive in this case. *See BP Chems.*, 4 F.3d at 980 ("Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive." (internal citation omitted)); *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985) ("The prior patent litigation initiated by Semi-Alloys in 1975, against two other parties unconnected with Indium, was too remote to make Indium's apprehension of further litigation in 1982 reasonable ....").

In order for this case to be one fit for judicial review, Teva must be able to demonstrate that it has a reasonable apprehension of *imminent* suit. Whether there is an "actual controversy" between parties having adverse legal interests depends upon whether the facts alleged show that there is a substantial controversy between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Casualty*, 312 U.S. at 273. This requirement of imminence reflects the Article III mandate that the injury in fact be "concrete," and "actual or imminent, not conjectural or hypothetical." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998). Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination, either of which would trigger Ivax's 180-day exclusivity period before Ivax is in a position to take advantage of the period by beginning commercial marketing of its generic sertraline drug upon expiration of the '518 patent. In any event, Pfizer need not sue Teva immediately, because Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006. Because Teva is unable

to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent, we cannot say that the district court erred in its application of the two-part test for determining whether an actual controversy exists in a patent infringement action.

III.

Teva also argues, however, that the Medicare Amendments establish jurisdiction without regard to the reasonable apprehension prong of the traditional two-part test. Although the Medicare Amendments were not in place when this case was before the district court, Congress provided that the provisions dealing with declaratory judgments would "apply to any proceeding ... that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced ...." Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1101(c)(1), 117 Stat. at 2456. Since the district court did not issue its opinion until December 8, 2003, the date the Medicare Amendments were enacted, the declaratory judgment provisions apply to this case.

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) so that it reads as follows:

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection

> (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5) (Supp. 2004). Thus, the Amendments explicitly state that an ANDA filer who submits a paragraph IV certification with respect to a patent listed in the Orange Book may, "consistent with the Constitution," bring a declaratory judgment action with respect to the patent if the patent owner does not bring an infringement action within the statutory forty-five day period.[7]

Teva argues that, in view of the Medicare Amendments, its declaratory judgment suit presents a justiciable controversy under Article III. In making this argument, Teva starts from the premise that, in its words, the reasonable apprehension test serves "primarily prudential not constitutional concerns." (Br. for Teva at 52.) It then posits that, in the Medicare Amendments, Congress directed courts to exercise jurisdiction over declaratory judgment actions

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[7] Prior to the Medicare Amendments, there was no prohibition against an ANDA filer bringing a declaratory judgment action upon expiration of the forty-five day period.

such as this to the limits of Article III. Joined by Amicus Curiae the Federal Trade Commission ("FTC"), Teva urges that it has suffered injury independent of the threat of an infringement suit because the 180-day exclusivity period itself has major economic consequences in the case of a drug such as Zoloft®. Teva and the FTC argue that there is a clear connection between this injury and actions already taken by Pfizer. They contend that if Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have the opportunity to gain access to the Zoloft® market during the 180-day period that will follow the expiration of the '518 patent.

As a preliminary matter, we do not agree with Teva that the reasonable apprehension of suit test represents a prudential rule rather than a constitutional requirement. In *EMC,* we squarely stated that we developed the two-part inquiry, of which the reasonable apprehension of suit test is one of the parts, "to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity." 89 F.3d at 811. Teva, nevertheless, points to statements in several of our cases that it argues demonstrate that the test is, in fact, merely a prudential rule. *See Arrowhead,* 846 F.2d at 736 (stating that the two-part test is a "test often useful in evaluating complaints for declaratory judgments in patent cases"); *Fina Oil Chem. Co. v. Ewen,* 123 F.3d 1466, 1470 (Fed. Cir. 1997) ("Satisfaction of th[e] traditional two-part test is not ... a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement.");

Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1327 (Fed. Cir. 1998) (stating that the two-part test "contributes to policing the boundary between a constitutional controversy ... and 'a difference or dispute of a hypothetical or abstract character.'" (citation omitted)).

We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement. First, there is nothing in *Arrowhead* that supports that proposition. In *Arrowhead*, the court made clear that although the "actual controversy" test in suits requesting a declaration of patent noninfringement or invalidity has been stated in various ways depending on the particular facts at hand, "the test requires two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement." *Arrowhead*, 846 F.2d at 737. At the same time, the statement from *Fina Oil* upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d at 1470. Under these circumstances, the statement at most suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met.[8] The statement in no way suggests that the traditional test does not address the Article III requirement of an actual case or controversy. Finally, the statement Teva quotes from *Hunter Douglas*, 153 F.3d at 1327, is really just another way of saying what we said in

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[8] In *Fina Oil*, the plaintiff sought a declaration that the inventors were properly named on the patent at issue in accordance with 35 U.S.C. § 116 (1994). The statement relied upon by Teva merely reflects that the precise formulation of the constitutional inquiry may vary depending on the facts of a given case.

EMC in expounding on the traditional two-part test: "This court's two-part test for declaratory judgment jurisdiction is designed to police the sometimes subtle line between cases in which the parties have adverse interests and cases in which those adverse interests have ripened into a dispute that may properly be deemed a controversy." 89 F.3d at 811. We would only add that we think this case presents just the sort of situation to which the *EMC* court alluded: Pfizer and Teva certainly have adverse interests. However, for a variety of reasons, their adverse interests have not ripened into an actual controversy.

Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman setting. The plain language of the amended statute—that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution"—compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's. The legislative history of the Medicare Prescription Drug, Improvement, and Modernization Act supports this view. In the version of the legislation originally introduced in the Senate (S.1) in the 108th Congress, it was provided that the filing of a paragraph IV certification, and the failure of the patentee or NDA-holder to bring an infringement action within forty-five days after the receipt of notice,

> shall establish an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in the courts of the United States in any action brought by the applicant under section 2201 of title 28 for a declaratory judgment that any

> patent that is the subject of the certification is invalid or not infringed.

Thus, as introduced, the legislation would have embodied the concurring opinion of Judge Gajarsa in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories,* 289 F.3d 775, 784 (Fed. Cir. 2002). Judge Gajarsa suggested that "the two acts of (1) a patentee listing a patent in the Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of noninfringement." *Id.* at 791. However, after changes made in conference, the legislation that became law in the 108th Congress (H.R. 1) did not contain language automatically conferring subject matter jurisdiction in the district courts anytime a patent is listed in the Orange Book, a paragraph IV certification is filed with respect to the patent, and a patentee fails to bring suit for infringement within forty-five days of receipt of notice of the certification.

The Conference Committee Report on H.R. 1 states as follows:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., Fina Oil and Chemical Co. v. Ewen, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., Vanguard Research, Inc. v. Peat, Inc., 304 F.3d 1249, 1254 (Fed. Cir. 2002).[9] In any given case, the conferees expect a court may or may not find a

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[9] In *Vanguard Research*, while the patentee, Peat, had not made an express threat of litigation, it had (1) sought to enjoin the potential infringer, Vanguard, from production of the potentially infringing technology by filing suit against it on other grounds, (2) had written Vanguard a letter indicating that it no longer had the right to market the potentially infringing technology, and (3) had contacted the U.S. Army and Congress implying to them that Vanguard was using Peat's technology without Peat's permission. 304 F.3d at 1254. The court held that, based on the totality of circumstances, there was a reasonable apprehension of suit on the part of Vanguard.

> reasonable apprehension of suit where these two specific factors are present.

H.R. Conf. Rep. No. 108-391 at 836 (2003).

We conclude that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. Our traditional two-part test remains good law, and, as discussed above, we see no error in the district court's application of the test.

Teva nevertheless points to the statement in the Conference Committee Report that "the conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act." According to Teva, making the declaratory judgment inquiry turn on the imminence of an infringement suit renders the test subject to manipulation by the patentee, thereby undermining the goals of the Hatch-Waxman Amendments to resolve patent disputes promptly once the issues are joined by the listing of a patent in the Orange Book and the serving of a paragraph IV certification with respect to the patent. Teva argues that these goals are not being served in this case. Teva points out that in view of Pfizer's settlement with Ivax, it is in Pfizer's interest to not expose the '699 patent to litigation, because doing so would raise the possibility of a determination of invalidity or non-infringement, either of which might trigger the commencement of Ivax's 180-day exclusivity period before the expiration of the '518 patent, in which event the exclusivity period would be useless. Teva asserts, for example, that if Pfizer can avoid triggering Ivax's 180-day

exclusivity period until the expiration of the '518 patent, it can expect to enjoy six months selling Zoloft® with only one, royalty-paying generic competitor, Ivax. At the same time, if the '699 patent were held invalid or not infringed, it would mean that during the six-month period following the expiration of the '518 patent on June 30, 2006, Pfizer would face competition in the Zoloft® market, not only from Ivax, but from other generic manufacturers as well. These circumstances, Teva urges, constitute injury to it, because the effect of Pfizer's not bringing suit against Teva is to prevent Teva from challenging the '699 patent and thereby possibly opening the door to its being able to sell generic sertraline hydrochloride during the 180-day exclusivity period following expiration of the '518 patent.

With these same considerations in mind, the FTC states that "while in a 'classic patent declaratory judgment suit,' the ordinary two-part test is appropriate" (Br. for FTC at 17 (quoting *Fina Oil,* 123 F.3d at 1466)), a case such as the present one presents a different situation: "[I]n the Hatch-Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme." (Br. for FTC at 17-18.)

We are not persuaded by Teva's and the FTC's arguments. Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not established that an actual controversy exists between it and Pfizer. The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity

period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.

If it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly. Until it does so, however, we must apply the statutory scheme as written. *See Reid v. Dep't of Commerce*, 793 F.2d 277, 284 (Fed. Cir. 1986) ("'The remedy for any dissatisfaction with the results in a particular case lies with Congress' and not this court, 'Congress may amend the statute; we may not.'")(quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576 (1982)). Thus, it is not for us to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases. That is what we would have to do in order to rule in favor of Teva in this case. That is because, in order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage vis-a-vis Ivax. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

CONCLUSION

For the foregoing reasons, we agree with the district court that Teva failed to establish that an actual controversy existed between it and Pfizer, as required under the Declaratory Judgment Act, 28 U.S.C. § 2201(a). We therefore affirm the court's dismissal of Teva's declaratory judgment suit for lack of jurisdiction.

AFFIRMED

MAYER, Circuit Judge*, dissenting.

Because the filing of a New Drug Application (NDA) and subsequent listing of a pharmaceutical patent in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") is conduct giving rise to a reasonable apprehension that an Abbreviated New Drug Application (ANDA) filer and declaratory judgment plaintiff will face a patent infringement suit, I respectfully dissent.

I.

Our traditional two-part test to determine whether an actual controversy exists in a patent infringement suit requires that "(1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the

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* Haldane Robert Mayer vacated the position of Chief Judge on December 24, 2004.

patentee will bring suit if the activity in question continues." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § § 355, 360cc, and 35 U.S.C. § 156, 271, 282), part one is satisfied in every instance where an ANDA is filed in accordance with 21 U.S.C. § 355(j), because 35 U.S.C. § 271(e)(2) provides that such a filing constitutes an act of infringement sufficient to trigger a justiciable case or controversy. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78 (1990) (determining that the purpose for creating an act of infringement in 35 U.S.C. § 271(e)(2) was to "eliminat[e] the de facto extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly"); *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed .Cir. 1997).

We have never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy. Conversely, we have consistently held that "there is no specific, all-purpose test" for determining the existence of a case or controversy, either. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (describing the traditional two-part test as "often useful in evaluating complaints for declaratory judgments" but not mandatory in every instance). We have clarified that the "[s]atisfaction of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action. Indeed, the two elements merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate

enough to fulfill the 'actual controversy' requirement." *Fina Oil,* 123 F.3d at 1470.

Regardless of whether the two-part test is a constitutional necessity or not, the legislative history voices Congress' intent to apply the "reasonable apprehension" portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. *See* H.R. Conf. Rep. No. 108- 391, at 836 (2003) ("Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction."). "As in all cases our task is to interpret the words of [the statute] in light of the purposes Congress sought to serve." *Chapman v. Houston Welfare Rights Org.,* 441 U.S. 600, 608 (1979).

II.

Because Teva filed an ANDA pursuant to 21 U.S.C. § 355(j) against Pfizer's '699 patent listed in the Orange Book, our application of the traditional test for an "actual controversy" turns solely on whether Pfizer has taken actions that give rise to a reasonable apprehension that it will sue Teva for infringement. The trial court dismissed Teva's declaratory judgment claim saying that no "actual controversy" existed under the Declaratory Judgment Act because, it concluded, Teva faced no "reasonable apprehension" that Pfizer would bring suit against it for infringing the '699 patent. *Teva Pharms. USA, Inc. v. Pfizer, Inc.,* No. 03-CV-10167, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

The 2003 amendments to the Hatch-Waxman Act provide for declaratory relief when an owner of a patent listed in the Orange Book fails to bring an infringement suit within 45 days after the ANDA is filed. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("Medicare Amendments") (codified in pertinent part at 21 U.S.C. § 355(j)(5)(C)(i)). These Medicare Amendments also give courts the authority to exercise jurisdiction over declaratory judgment actions brought by generic infringers "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) (2003).

The Declaratory Judgment Act authorizes declaratory relief only in a "case of actual controversy." 28 U.S.C. § 2201 (2000). This requirement is the same as the "case or controversy" requirement of Article III of the Constitution. *See Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha,* 57 F.3d 1051, 1053 (Fed. Cir. 1995) ("The purpose of the declaratory action is to permit a threatened party to resolve its potential liability, but only when the relationship has progressed to an actual controversy, as required by Article III of the Constitution."). The Supreme Court has long held "that whatever else the 'case or controversy' requirement embodied, its essence is a requirement of 'injury in fact.'" *Schlesinger v. Reservists Comm. to Stop the War,* 418 U.S. 208, 218 (1974) (citation omitted).

The Supreme Court also has established criteria for evaluating whether a case passes the constitutional threshold of being a "case or controversy." In *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace,* 288 U.S. 249, 259 (1933), the Court determined that it should "look not to the label which the Legislature has attached to the procedure

followed in the state courts, or to the description of the judgment which is brought here for review, in popular parlance, as 'declaratory,' but to the nature of the proceeding which the statute authorizes, and the effect of the judgment rendered upon the rights which the appellant asserts." Similarly, the Court in *Aetna Life Insurance Co. v. Haworth* decided that the federal Declaratory Judgment Act validly conferred jurisdiction on federal courts to issue declaratory judgments in appropriate cases. 300 U.S. 227 (1937). The Court "observed that the controversy would admit 'of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Calderon v. Ashmus,* 523 U.S. 740, 746 (1998) (quoting *Aetna,* 300 U.S. at 241). Important to this case, the Court has "thus recognized the potential for declaratory judgment suits to fall outside the constitutional definition of a 'case' in Article III: a claim 'brought before the court(s) for determination by such regular proceedings as are established by law or custom for the protection or enforcement of rights, or the prevention, redress, or punishment of wrongs.'" *Id.* (quoting *Fairchild v. Hughes,* 258 U.S. 126, 129 (1922)). Such is the scheme created by the jurisdictional directives of Congress in the enactment of Hatch-Waxman and corresponding Medicare Amendments—the key issue being whether the courts are capable of achieving a final or conclusive determination that resolves the entire case or controversy.

Finding an actual controversy within the meaning of the Declaratory Judgment Act requires an analysis of the totality of the circumstances of each case. *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed. Cir. 2004). The facts alleged must show a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *Id.*

"Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002) (citations omitted). Determining whether a reasonable apprehension of suit exists in a case controlled by the statutory and regulatory scheme of Hatch-Waxman requires a thorough analysis of the consequences and repercussions of each party's actions.

The most important basis for finding a reasonable apprehension of suit is Pfizer's listing of the '699 patent in the Orange Book. Pfizer's listing constituted an affirmative representation to the FDA and to competitors that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of any generic sertraline hydrochloride drug covered by the claims of the '699 patent. 21 U.S.C. § 355(b)(1) (2003). Although the listing in the Orange Book is a standard requirement for filing a NDA, it is a requirement that expresses a party's future intent to enforce its patent rights against those who subsequently file an ANDA and infringe. We have explained that the "reasonable apprehension" test serves to "protect[ ] quiescent patent owners against unwarranted litigation." *Arrowhead*, 846 F.2d at 736. Pfizer is not a defendant that "has done nothing but obtain a patent." *Id.* By listing its patent in accordance with 21 U.S.C. § § 355(b)(1) & (c)(2), Pfizer has informed the world that the '699 patent likely precludes anyone from marketing a generic sertraline hydrochloride product until it expires.

In evaluating whether there is a controversy, courts must take into account the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product. Hatch-Waxman establishes that the first generic

applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) a "decision of a court ... holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv)(I-II). A court decision has been defined to include any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise. *See 3M v. Barr Labs., Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002). If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

Although Congress' intention was for Hatch-Waxman to promote competition and speed generic entry into the market, the opposite has occurred as a result of strategies to "park" the 180-day period. Brand-name drug manufacturers may enter into an agreement with the first ANDA applicant whereby the first ANDA applicant agrees to refrain from entering the market for some period of time if the brand-name firm forgoes suing subsequent ANDA applicants during the statutory 45-day period. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until: (i) 180 days after the first ANDA applicant

enters; (ii) the relevant patent expires; or (iii) a subsequent ANDA applicant can itself trigger the 180-day period. Essentially, the framework of Hatch-Waxman, combined with the conduct of the brand-name manufacturer, creates a cognizable injury to the subsequent generic ANDA filer. The delay created directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market. The only way to eliminate this problem is for the subsequent ANDA applicant to bring a declaratory judgment action seeking a court decision of invalidity or noninfringement of the relevant patent.

Taking into account the specific regulatory context of the Hatch-Waxman regime, the "reasonable apprehension" test applied "to the extent consistent with the Constitution" is satisfied by Pfizer's conduct. *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) ("[A] declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction" and the courts should "examine as part of their analysis the particular policies served by the Hatch-Waxman Act."). Cases arising under Hatch-Waxman do not present a classic patent declaratory judgment suit, and accordingly, the reasonable apprehension test should not be applied in the traditional manner. *See Fina Oil,* 123 F.3d at 1470 (discussing classic patent declaratory judgment suits). Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In contrast, within the Hatch-Waxman regime, a subsequent ANDA applicant is not free to market-the applicant may suffer direct legal injury and require judicial relief based on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents and the likelihood of a future patent suit after the running of the 180-day period.

Against the backdrop of Hatch-Waxman, the totality of Pfizer's conduct must also be considered. *See* H.R. Conf. Rep. No. 108-391, at 836 (2003) ("In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where [an ANDA has been filed with a Paragraph IV certification and the patentee has not brought an infringement suit within 45 days]."). First, Pfizer sued Ivax, the first generic manufacturer of sertraline hydrochloride. This shows both Pfizer's belief that its '699 patent is valid and its intent to assert the patent against infringers. "Related litigation may be evidence of a reasonable apprehension." *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992). Pfizer also has a history of asserting its patent rights against infringers of other patents. Considering that the '699 patent, which covers the brand name drug Zoloft ®, produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit. Finally, Pfizer refused to grant Teva a covenant not to sue for infringement of the '699 patent.

Allowing Teva's declaratory judgment action is consistent with the "case or controversy" requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between Teva and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman regime, Teva's injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, Teva

maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.

Appendix B — Opinion of the United States District Court for the District of Massachusetts Granting Defendant's Motion to Dismiss Filed December 8, 2003

United States District Court
District of Massachusetts

Civil Action No. 03-CV-10167-RGS

TEVA PHARMACEUTICALS USA, INC.

v.

PFIZER INC.

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO DISMISS

December 8, 2003

STEARNS, D.J.

On January 24, 2003, Teva Pharmaceuticals USA, Inc. (Teva), a manufacturer of generic pharmaceuticals, brought this declaratory judgment action against Pfizer Inc., seeking a determination that its generic version of sertraline hydrochloride would not infringe Pfizer's patented version of the drug, which is sold under the trade name Zoloft®. On March 10, 2003, Pfizer moved to dismiss the action, arguing that the court lacked subject matter jurisdiction because of

the absence of an actual controversy between the parties.[1] On November 6, 2003, the court heard oral argument on the motion to dismiss.

The Hatch-Waxman Act

This dispute arises under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (FFDCA), the complexities of which were explained by the Federal Circuit in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-1371 (Fed. Cir. 2002), as set out below.[2]

> Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, (the "Hatch Waxman Amendments" to the Federal Food, Drug and Cosmetic Act ("FFDCA")), Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market. Under the Hatch Waxman Amendments, a manufacturer that seeks to

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1 After the initial briefing, the parties filed supplemental briefs to address a recent decision in a nearly identical case, Dr. Reddy's Laboratories, Ltd. v. Pfizer Inc., 2003 WL 21638254 (D.N.J., July 8, 2003).

2 The internal statutory citations to the FFDCA in *Andrx* were substantially modified by the recent revision of the Medicare law. The Medicare amendments, however, do not alter the substance of the ANDA process.

market a generic drug may submit an ANDA [Abbreviated New Drug Application] for approval by the FDA, rather than submitting a full New Drug Application ("NDA") concerning the safety and efficacy of the generic drug, and it may rely on safety and efficacy studies previously submitted by the pioneer manufacturer by submitting information showing the generic drug's bioequivalence with the previously approved drug product. *See* 21 U.S.C. § 355(j)(2)(A).

Also under the Hatch-Waxman Amendments, a pioneer drug manufacturer that holds an approved NDA is required to notify the FDA of all patents that "claim [ ] the drug for which the [NDA] applicant submitted the application...." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations (otherwise known as the "Orange Book"). Under 35 U.S.C. section 71(e)(1), it is not patent infringement to conduct otherwise infringing acts necessary to prepare an ANDA. Under section 271(e)(2), however, a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent. As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug. 21 U.S.C. § 355(j)(2)(A)(vii).... [T]he ANDA applicant must certify that (I) no such patent information has been submitted to the FDA;

> (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). These are commonly referred to as paragraph I, II, III, and IV certifications.
>
> When an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is not infringed, invalid, or unenforceable. 21 U.S.C. § 355(j)(2)(B)(i); 21 C.F.R. § 314.95(c)(6). The patentee then has forty-five days to sue the ANDA applicant for patent infringement, and the ANDA applicant may not file a declaratory judgment during this time (based on the filing of the ANDA application). 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee does not sue, the ANDA will be approved. If the patentee does file suit, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier.

The FFDCA provides an incentive to the first drug manufacturer who files an ANDA paragraph IV certification challenging a patent listed in the Orange Book. Under section 355(j)(5)(B)(iv), a 180-day period of marketing exclusivity is triggered by "the Secretary['s] receiv[ing] notice from the [first ANDA applicant] of [its] first commercial marketing of the drug" or by "a decision of a court in an action described

in [21 U.S.C. § 355(j)(5)(B)(iii)] holding the patent which is the subject of the certification to be invalid or not infringed." *Minnesota Mining and Mfg. Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002).

FACTS

Pfizer holds two patents on Zoloft®: U.S. Patent No. 5,248,699 (the '699 patent), and U.S. Patent No. 4,356,518 (the '518 patent). The '518 patent will expire on June 30, 2006.[3] The '699 patent expires on September 28, 2010. Pfizer has listed both patents in the Orange Book.

In July of 2002, Teva filed an ANDA, pursuant to 21 U.S.C. § 355(j), seeking the FDA's approval to market its generic version of sertraline hydrochloride. Teva also filed a paragraph III certification stating that it would not market the generic until Pfizer's '518 patent expired on June 30, 2006. Teva simultaneously filed a paragraph IV certification contending that its generic does not infringe the '699 patent or, alternatively, that the '699 patent is invalid.[4] On January 24, 2003, Teva filed this Complaint seeking a declaratory judgment of invalidity/non-infringement.

Teva was not the only manufacturer to file a sertraline hydrochloride ANDA. In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as Ivax, filed the first sertraline hydrochloride ANDA. Like Teva, Ivax filed a paragraph III certification disclaiming any intention of

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[3] The '518 patent was to expire on December 30, 2005. The FDA, however, granted Pfizer a six month pediatric exclusivity extension.

[4] There is a third related Pfizer patent which is not implicated by Teva's filing.

selling the drug prior to the expiration of the '518 patent, as well as a paragraph IV certification challenging the '699 patent. As the first ANDA filer, were Ivax to prevail in the patent action, it would have been entitled under section 355(j)(5)(B)(iv) of the Act to a 180-day market exclusivity period. That period would begin to run either on the date of the first commercial sale of the generic drug, which given the paragraph III certification, would be June 30, 2006, or on the date of a court decision invalidating the '699 patent. In response to the ANDA, Pfizer brought an infringement action against Ivax within the forty-five day "stay-put" period mandated by section 355(j)(5)(B)(iii). Pfizer and Ivax then settled the case, with Ivax taking the rights to the exclusivity period. According to Teva, the settlement gives Pfizer a vested interest in protecting Ivax's exclusivity rights. This is so, because unless an intervening court decision opens the market further, Zoloft® will face only one generic drug competitor during the exclusivity period.

After Ivax filed its ANDA, Dr. Reddy's Laboratories (DLR) filed its own sertraline hydrochloride ANDA. Like Ivax and Teva, DLR challenged the '699 patent but not the '518 patent. Pfizer opted not to file suit against DRL within the "stay-put" period, causing DRL to bring an action for declaratory judgment in the district court in New Jersey. Pfizer then filed a motion to dismiss, similar in all respects to the motion pending before this court. On July 7, 2003, Judge Pisano allowed Pfizer's motion, holding that DRL had not demonstrated a reasonable apprehension of suit and that as a result no actual controversy existed between the parties. *Dr. Reddy's Laboratories, Ltd. v. Pfizer Inc.*, 2003 WL 21638254, at *6 (D.N.J., July 8, 2003).

DISCUSSION

"Under the Declaratory Judgment Act, 28 U.S.C. § 2201(a) (1994), a district court has jurisdiction over a declaratory judgment action only when there is an 'actual controversy.'" *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). "For an actual controversy to exist, '[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.'" *Id.* "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). Hence, two question are before the court. Has Teva satisfied the two prongs of the "actual controversy" test and, if so, should the court exercise jurisdiction?

It is clear that Teva has satisfied the second prong of the test by filing the ANDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). ("[Section] 271(e)(2) provided patentees with a defined act of infringement [filing an ANDA] sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity."). *See also Andrx Pharmaceuticals, Inc.*, 276 F.3d at 1371 ("[U]nder section 271(e)(2), ... a generic drug manufacturer infringes a

patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent.").[5]

Whether Teva satisfies the first prong of the "actual controversy" test, requiring "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit," is more problematic. "To put a putative infringer in reasonable apprehension of suit does not require an express charge of infringement and threat of suit; rather, such apprehension may be induced by subtler conduct if that conduct rises 'to a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent,' *i.e.*, to initiate an infringement action." *EMC Corp.*, 89 F.3d at 811.

Teva, like DRL in *Dr. Reddy's Laboratories*, argues that Pfizer's actions (or inactions) to date have created a reasonable apprehension of suit. Teva cites the following indices of aggression: (1) Pfizer has listed the '699 patent in the Orange Book; (2) Pfizer has refused to grant Teva a covenant not to sue; (3) Pfizer has aggressively asserted its patent rights against alleged infringers of other of its patents; (4) Pfizer sued Ivax, the first generic manufacturer of

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[5] Section 271(e)(2) was intended to define a technical act of infringement for jurisdictional purposes to permit patent holders to bring suit against an ANDA filer within the forty-five day "stay-put" period. Conversely, the same jurisdictional act of infringement serves the ANDA filer when it seeks to file a declaratory judgment action after the forty-five day period expires. As Judge Pisano pointed out in *Dr. Reddy's Laboratories*, at *5, Pfizer's reliance on *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), and *Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F. Supp. 2d 606, 619 (D.N.J. 2000), is misplaced as *Telectronics* is factually distinct, and *Bristol-Myers Squibb* did not address the import of section 271(e)(2).

sertraline hydrochloride; and (5) it is in Pfizer's self-interest "to leave a cloud of litigation" hanging over Teva as a means of protecting Ivax's 180-day exclusivity period.[6]

Like Judge Pisano in *Dr. Reddy's Laboratories*, I find that Teva has not satisfied the first prong of the "actual controversy" test. Teva argues that by listing a patent in the Orange Book, a patentee has declared its intention to sue any potential infringer. A blanket inference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue.

Teva also points to Pfizer's refusal to enter a covenant not to sue. According to Teva, Pfizer has no reason not to sign the covenant (if it does not intend to sue) and by refusing to do so, has indicated its belief that it has substantive grounds on which to bring suit. Finally, Teva

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[6] Teva also argues that Pfizer returned without testing samples of the generic that Teva had mailed to Pfizer's counsel after the suit was filed. "Pfizer knows that testing would force its hand—either it would be required to tell Teva that it does not infringe its patent and provide it with a covenant not to sue, or to come clean with its intention to sue Teva for infringement." Teva Supplemental Memorandum, at 2. Whatever force this argument might have in the abstract—Pfizer maintains that it has no legal obligation to undertake an investigation of a competitor's product—it does not change the fact that it was Teva, and not Pfizer, who precipitated the product testing issue. Pfizer simply chose not to respond. This can hardly be considered conduct that exemplifies a "degree of adverseness" sufficient to trigger an actual controversy. *EMC Corp.*, 89 F.3d at 811-812. *Cf. Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992) (no apprehension of suit where patentee was approached by declaratory judgment plaintiff, and patentee did no more than defend the validity of its patent during negotiations).

maintains that Pfizer's foot-dragging in declaring its intentions one way or another is simply intended to forestall a court decision that might prematurely start the running of Ivax's market exclusivity period.[7] The bottom line is that there is nothing in the FFDCA that requires Pfizer to respond one way or another to Teva's request for a covenant not to sue. Nor is the fact that Pfizer may have an interest in seeing Ivax preserve its six-month quasi-monopoly relevant, given the intent of the Hatch-Waxman Amendments to encourage challenges to market-dominating pharmaceutical patents by so rewarding first filers. If anything, Pfizer's self-interest in protecting Ivax's exclusivity period makes the prospects of a lawsuit against Teva (or anyone else) even more remote.

Thus, all that remains is Teva's belief that it will be sued because Pfizer sued Ivax. This subjective belief does not amount to "an explicit threat or other action by the *patentee*" indicating the imminence of a lawsuit. *Amana Refrigeration*, 172 F.3d at 855 (emphasis added). It may well be, as Teva alleges, that Pfizer has outmaneuvered Teva by effectively partnering with Ivax. If so, Teva's frustration is understandable. But there is nothing in the FFDCA that makes Pfizer's conduct actionable.

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[7] Pfizer argues that this is a case of the pot calling the kettle black as Teva's obvious motive in filing this action is to rob Ivax of the benefits of its first filer status.

ORDER

For the foregoing reasons, Pfizer's motion to dismiss is *ALLOWED*. The dismissal will be entered without prejudice.

SO ORDERED.

/s/ Robert G. Stearns

United States District Judge

Appendix C — Opinion of the United States Court of Appeals for the Federal Circuit Denying Petition for Panel Rehearing and Rehearing En Banc Filed April 4, 2005

United States Court of Appeals for the Federal Circuit.

04-1186

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by the Appellant, and a response

thereto was invited by the court and filed by the Appellee.[1] The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amici curiae briefs were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on April 11, 2005.

MAYER, GAJARSA, and DYK, Circuit Judges, would rehear the appeal en banc.

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissents in a separate opinion.

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[1] Amicus curiae briefs were filed by:

1- The Federal Trade Commission.

2- The Generic Pharmaceutical Association.

3- Ivax Pharmaceuticals, Inc.

4- United States Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissents in a separate opinion.

FOR THE COURT

April 4, 2005
Date

s/ Jan Horbaly
Jan Horbaly
Clerk

GAJARSA, Circuit Judge, with whom DYK, Circuit Judge, joins, dissenting from the order declining rehearing en banc.

The Court has denied the petition to review this case *en banc*. I must respectfully dissent from that denial. This is a critical issue under the Hatch-Waxman Act.[1] The failure of this court by *en banc* action to correct the *Teva* court's decision, 395 F.3d 1324 (Fed. Cir. 2005), allows the statutory procedures to be manipulated by the patent holders to the clear and foreseeable detriment of the generic drug industry.

The *Teva* court's reasonable apprehension analysis is the wrong test for a concrete, actual, or imminent injury in fact when considering the problem of a generic with a

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[1] The Patent Laws and Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271 and 282 (2000)), *as amended by* Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)).

second-filed ANDA certification.[2] Article III does not compel it, and the Supreme Court has rejected the doctrinal rigidity that *Teva* introduces. Our cases recognize reasonable apprehension, in the typical patent infringement case, as but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of law. The ANDA facts correspond to the typical infringement case in name only, and it is this court's constitutional duty to look at those facts in their proper context. The *Teva* court's misguided Article III analysis further thwarts Congress's clear intent to foster, through the detailed provisions of Hatch-Waxman, greater competition in generic pharmaceuticals.

I.

The question is whether Teva has shown a justiciable case or controversy within Article III. Congress unambiguously swept aside any additional limitation on jurisdiction potentially introduced by the Declaratory Judgment Act, 28 U.S.C. § 2201.

> [T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

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[2] The overall scheme of the Hatch-Waxman Act is described in detail in our decisions in *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) and *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

35 U.S.C.A. § 271(e)(5) (West Supp. 2004), as added by Pub. L. 108-173, 117 Stat. 2457 (Dec. 8, 2003). The law is clear that this justiciability issue has three elements: (1) a concrete, actual or imminent injury in fact; (2) fairly traceable causation between the injury and defendant's conduct; and (3) redressability. *See Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 103-04 (1998); *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.,* 454 U.S. 464, 472 (1982). Only the concrete injury in fact is disputed.

The cases treat the controversy requirements of Article III and § 2201 together and their approach is instructive here. Jurisdiction under § 2201 can be no broader than jurisdiction under Article III, yet the cases show that § 2201 is very broad indeed. Article III is no narrower. *See Aetna Life Ins. Co. of Hartford, Conn. v. Haworth,* 300 U.S. 227, 240 (1937) (§ 2201 "has regard to the constitutional provision and is operative only in respect to controversies which are such in the constitutional sense[.]"). As the Supreme Court recognizes, the § 2201 controversy requirement is highly fact specific.

> The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy. Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient

> immediacy and reality to warrant the issuance of a declaratory judgment.

Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). The Supreme Court,[3] this court,[4] and our sister circuits[5] consistently apply this holding by looking to all the circumstances surrounding a controversy.

A.

The *Teva* majority opinion does not, and its reasons for failing to do so are not convincing. In far more difficult factual contexts the courts have nonetheless found "a concrete, actual or imminent injury in fact" satisfying Article III. In *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59 (1978), for example, the appellees challenged the constitutionality of the Price-Anderson Act. By that Act, Congress limited the aggregate tort liability of nuclear power plant operators for a single nuclear "incident." The appellant

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[3] *See Steel Co.*, 523 U.S. at 103-04; *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 81 (1978) (finding actual case and controversy where plaintiffs would sustain injury from operation of planned nuclear power plant, and injury was redressable by constitutionality challenge to Price-Anderson Act).

[4] *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy).

[5] *See, e.g., Riva v. Mass.*, 61 F.3d 1003, 1009-10 (1st Cir. 1995); *Kidder, Peabody & Co., Inc. v. Maxus Energy Corp.*, 925 F.2d 556, 562-63 (2d Cir. 1991); *Oneida Tribe of Indians of Wis. v. State of Wis.*, 951 F.2d 757, 760 (7th Cir. 1991).

was a utility that was *constructing* nuclear power plants. The appellees, including persons "who live within close proximity of the *planned* facilities," challenged the statute under the Fifth Amendment. *Id.* at 67 (emphasis added). Their theory was that "*in the event of a nuclear accident* their property *would be* 'taken' *without any assurance* of just compensation." *Id.* at 69 (emphasis added). The court concluded that this theory stated a justiciable Article III controversy. *See id.* at 81 ("[A]ppellees will sustain immediate injury from the operation of the disputed power plants.").

The breadth of Article III standing in environmental cases sharply contrasts with the *Teva* court's narrow construction in this ANDA context. The Supreme Court has held that a concrete injury in fact, for Article III, is shown where a non-profit's members allege that a polluter's discharges, "and the affiant members' *reasonable concerns about the effects* of those discharges, directly affected those affiants' recreational, aesthetic, and economic interests." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 183-84 (2000) (emphasis added). The Court expressly ruled that conditional statements—that members would use a river for recreation if Laidlaw stopped discharging pollutants into it—sufficed to show concrete injury in fact under Article III. *Id.* at 184. Teva's injury in this case, by comparison, is far more immediate.

The facts showing Teva's "concrete, actual or imminent injury" are far easier to identify. Ivax filed the first ANDA on the active ingredient for Zoloft; Teva filed a subsequent or second ANDA. Teva certified that its proposed formulation would not infringe Pfizer's U.S. Patent No. 5,248,699, or that the patent was invalid. Pfizer had 45 days to sue Teva for this patent infringement, 35 U.S.C.

§ 271(e)(2)(A), and did not. Although Pfizer had sued Ivax, they settled out of court. Pfizer granted Ivax a royalty bearing license for the '699 patent, preserved Ivax's 180 day statutory exclusivity, and designed a comfortable duopoly set to begin on June 30, 2006 and potentially last 180 days past the '699 patent expiration in 2010. The FDA therefore could not approve Teva's generic drug until 180 days after Ivax's exclusivity expired—when either the '699 patent expired or was invalidated—and without FDA approval Teva could not market its product.

By settling with Ivax, Pfizer leveraged the Hatch-Waxman exclusivity to insulate the '699 patent from any validity challenge. Pfizer also insulated itself from any judicial determination of the metes and bounds of its '699 patent claim scope in relation to a design-around, a determination central to the proper function of our patent system. Because of this insular effect, Pfizer effectively extended—as against all but Ivax—the term of its underlying U.S. Patent No. 4,356,518, which expires on June 30, 2006, to coincide with the '699 patent's later expiration in 2010.[6]

This ties up Teva's investment in its proposed generic until at least 2010, precludes it from testing a potentially weak patent, precludes it from triggering the statutory

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[6] That is, the '518 patent claims the active ingredient in Zoloft. The '699 patent is an improvement. A generic, like Teva, that could design around the '699 but not the '518—or that thought it had found invalidating art for the '699 patent—would need a license to the '518 patent to enter the market, or face an infringement action. Once the '518 patent expired, Teva could confidently enter the market with a compound that did not infringe the '699 patent. But because of the Hatch-Waxman exclusivity, Pfizer insulated the '699 patent from any test in litigation. In practice this extends the '518 patent term until the '699 patent expires.

exclusivity period with a successful validity challenge, and precludes it from introducing an effective design-around, as is its right and as the patent law encourages. The live controversy is found on the face of this bottleneck under the statute.[7] Any of this defines a concrete, actual or imminent injury in fact within the meaning of Article III, and on that basis Teva states a justiciable controversy under § 2201.

B.

None of these problems can be found in the typical patent infringement context, in which this court has regularly tested immediate injury in fact by the reasonable apprehension test. Consistent with *Maryland Casualty*, this court has never held that Article III required that analysis. Quite to the contrary, this court has repeatedly observed that reasonable apprehension was simply a functional approach to typical patent infringement problems under § 2201. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996) (quoting *Md. Cas.*); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) ("There is no simple rule that addresses all shades of relationships between disputants."); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735-36 (Fed. Cir. 1988) (observing "there is no specific, all-purpose test" for an actual controversy). The purpose of the reasonable apprehension analysis "is to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The *Teva* court

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[7] *Cf. Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n. 18 (D.C. Cir. 1998) ("It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.").

ignores this precedent and reads general infringement policy considerations into Article III, where they do not belong.

The contextual differences between the second ANDA filer and the typical patent infringement case make the reasonable apprehension test inappropriate for this action. By guiding the patentee's conduct in the typical case, the reasonable apprehension analysis allows the patentee to avoid litigation. Identifying a justiciable controversy in terms ~~of a threat~~ of infringement litigation, the doctrine establishes the circumstances in which the uncertainty of legal rights materially harm a potential infringer in the marketplace. The injury facing Teva in this case is different in kind, but no less actionable.

Teva's injury does not depend on threats from the incumbent. In view of the statute, the injury exists independent of any threat, and the policy motivation for applying the reasonable apprehension test is completely lacking. There is no sense in the court demanding the incumbent to brandish the threat of infringement actions, even beyond the act of listing a patent in the Orange Book, given a statutory system that encourages the incumbent to do everything possible to prevent its patents from being put in play. No incumbent will ever make the threat, if it can simply ride out the term in the listed patent.[8] From first principles, a fact specific analysis shows that the reasonable apprehension test is not designed for this case.

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[8] *See Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed. Cir. 2002).

II.

The language of § 271(e)(5) grants Article III jurisdiction to the maximum extent possible. The statute provides that the courts shall *have* subject matter jurisdiction. The majority's analysis in *Teva* of the legislative history to the 2003 Act[9] seems addressed to this point, but its reasoning is unconvincing.

The statute specifically provides that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action." The court, therefore, has a Congressional directive to refrain from applying any jurisdictional limitation crafted by the courts or found in § 2201. The *Teva* court overlooks this basic point.

The *Teva* court further focuses on the language originally introduced for § 271(e)(5), which provided that an incumbent's failure to sue within 45 days "shall establish an actual controversy between the applicant and the patent owner." *Teva,* 395 F.3d at 1336. In conference the language was changed to a provision that the courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over these actions. *Id.* The court concludes that § 271(e)(5) was "not meant to automatically bestow district court jurisdiction over actions such as Teva's." *Id.* This conclusion is contrary to the plain language of § 271(e)(5). The change in language bestowed full Article III jurisdiction and simply recognizes the court's role in declaring when the

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[9] Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)) [hereinafter "2003 Act"].

judicial powers under Article III extend to this action. It does not bear on the proper scope of Article III.

The *Teva* court also focuses on a Committee Report accompanying the modified 2003 Act. The language in the Report cannot contradict the plain language of § 271(e)(5). A legislative enactment cannot limit the judicial power under Article III, and, *a fortiori,* language in a Committee Report that misstates our Article III jurisprudence cannot bind this court.

Ultimately, the idea that § 271(e)(5) suggests a limitation on standing is misplaced, given the plain language of Hatch-Waxman. The statute provides an express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents. Under this statutory scheme, it is court challenges by generic drug companies that limit incumbent overreaching by submitting over-inclusive lists of patents applicable to any given branded formulation. Congress's intent to foster early generic market entry precludes any real argument for any limitation. Certainly under the circumstances of this case, Teva's declaratory action is the ideal method to police Pfizer's strategic manipulation of the Hatch-Waxman exclusivity provisions. Delayed resolution of the bottleneck facing Teva serves no purpose, as by then the patents at issue will have expired. There is no basis for precluding this suit on Article III grounds.

III.

The *Teva* court's Article III analysis distorts longstanding Supreme Court jurisprudence and misapplies the decisions of this court. Teva has presented a justiciable controversy, and the courts should decide it. Worst of all, the

Teva court's Article III analysis forestalls legislative correction. The court should have corrected this error *en banc*. I respectfully dissent from the refusal to do so.

DYK, Circuit Judge, with whom GAJARSA, Circuit Judge, joins, dissenting from the order denying rehearing en banc.

This case presents an important question under the Hatch-Waxman Amendments, which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc (2000) and 35 U.S.C. §§ 156, 271, 282 (2000))—whether a patent holder can delay Food and Drug Administration ("FDA") approval of an application for a competing generic drug by the simple expedient of refusing to sue for infringement. Here there is a present controversy over Teva's right to secure approval of its Abbreviated New Drug Application ("ANDA"), plainly adequate to satisfy the requirements of Article III.

The Declaratory Judgment Act, 28 U.S.C. § 2201 (2000), and the 2003 Medicare Amendments, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat. 2066, 2448-69 (codified in pertinent part at 21 U.S.C.A. § 355(j)(5)(C)(i) (West Supp. 2004) and 35 U.S.C.A. § 271(e)(5) (West Supp. 2004)), were designed to create a declaratory judgment remedy in circumstances permitted by Article III. The panel's holding, relying on earlier decisions of our court, that Article III bars such a remedy unless "a reasonable apprehension of *imminent* suit" exists is incorrect. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005). I dissent from the denial of rehearing *en banc*.

I.

The plain language of the 2003 Medicare Amendments requires that in the Hatch-Waxman context the federal courts allow declaratory judgment actions to the full extent allowed by Article III. 35 U.S.C.A. § 271(e)(5) ("[C]ourts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought ... under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). Even if the legislative history could be read as approving our reasonable apprehension test, that history cannot overcome the plain language of the statute. So we must decide whether Article III is satisfied.

There are relatively few Supreme Court cases dealing with Article III and declaratory judgments, but the few cases that do exist provide no support for a reasonable apprehension of imminent suit requirement. The declaratory judgment statute was designed to deal with a situation in which the declaratory judgment defendant declined to bring suit, i.e., in which there was no reasonable apprehension of imminent suit. The Supreme Court case upholding the statute involved just such a situation—one in which there was no imminent risk of suit because the potential plaintiff declined to sue. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937). In that case, the insured on several policies stopped making premium payments and made repeated claims for benefits on account of total and permanent disability. *Id.* at 237-38. Aetna refused to pay benefits because it contended that the insured was not disabled and that the policies had lapsed due to nonpayment. *Id.* at 238. The insured failed to bring suit, so Aetna filed for a declaratory judgment that the insured was not disabled and that the policies had lapsed. *Id.* at 239. The Court found that

these facts gave rise to a controversy within the meaning of Article III, stating "[t]here is here a dispute between parties who face each other in an adversary proceeding.... The dispute is defined and concrete, not hypothetical or abstract.... It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242.

Likewise, the Ninth Circuit, in a case in which the plaintiff faced a risk of liability rather than suit, has held that "[a]n action for a declaratory judgment ... is a case or controversy if the plaintiff has a real and reasonable apprehension that he will be subject to *liability,*" not suit. *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co., Inc.,* 655 F.2d 938, 944 (9th Cir. 1981) (emphasis added).[1] The First Circuit has even more directly addressed the issue in *Sallen v. Corinthians Licenciamentos LTDA,* 273 F.3d 14 (1st Cir. 2001), and adopted a view that conflicts with the panel decision in this case. There, a World Intellectual Property Organization ("WIPO") panel found Sallen to be a cybersquatter and ordered his domain name transferred to Corinthians Licenciamentos LTDA ("CL"). *Id.* at 21-22. Sallen filed suit in federal district court seeking a declaration that under United States law (which allowed a challenge to the WIPO decision) he was entitled to the domain name. *Id.* at 22. The district court dismissed the

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[1] That case involved a manufacturer that filed for declaratory judgment of invalidity of the defendant's patent after a potentially unauthorized person working for the defendant threatened a third party with suit if the third party purchased the plaintiff's equipment. *Id.* at 941, 944-45. The third party purchased the equipment. *Id.* at 941. A hold harmless provision in the contract between the third party and the plaintiff placed the plaintiff in reasonable apprehension of liability. *Id.* at 945.

case because CL had no intent to sue Sallen under United States law. *Id.* On appeal, the First Circuit rejected CL's argument that a reasonable apprehension of suit is required to satisfy Article III:

> CL claims that a reasonable apprehension of suit is required to meet Article III's case or controversy requirement. *But this is not the only way to establish the existence of a case for purposes of Article III. The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit.* That is not this case.

Id. at 25 (internal citations omitted and emphasis added). The court found that United States law "provides a registrant who has lost a domain name ... with a cause of action for an injunction returning the domain name if the registrant can show that she is in compliance with" United States law. *Id.* at 26. Thus, the court found that the controversy in issue was certain and that "a certain controversy renders the 'reasonable apprehension' question irrelevant." *Id.*

In my view, the First Circuit is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test. The panel here also reached the wrong result in this case by relying on that erroneous test.

II.

Here it seems to me that there are three potential controversies:

1. There is a potential controversy over whether the ANDA filing itself was an infringement. I doubt whether this, standing alone, satisfies Article III because Pfizer seems not to care whether such an infringement occurred. *Textron Lycoming Reciprocating Engine Div., AVCO Corp. v. UAW,* 523 U.S. 653, 661 (1998) (finding no constitutional controversy where the declaratory judgment defendant had no "interest in defending the binding nature of the contract").

2. There is also a potential controversy over whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement. The problem here is that Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from doing so by the risk of infringement damages. Instead, Teva alleges only that the filing of its ANDA constituted technical infringement; that Pfizer did not file suit within the 45-day period; that Pfizer included the '699 patent in the Orange Book; and that Pfizer tends to enforce its patents through litigation. (J.A. at 52.) Unless Teva actually is about to manufacture or sell the drug, there would seem to be no case or controversy under this theory. *Societe de Conditionnement,* 655 F.2d at 944.

3. The third potential controversy is over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing. In my view, there is a present and concrete controversy over Teva's right to such an approval, which satisfies the requirements of Article III. The Hatch-Waxman Amendments provide for the right to secure resolution of the controversy through a declaratory judgment.

Ivax earlier filed a paragraph IV certification regarding the '699 patent and then settled with Pfizer. Thus, Ivax will enjoy a 180-day exclusivity period beginning with

the *earlier* of (1) the first day it markets its generic drug (which cannot be earlier than June 30, 2006) or (2) the date that the '699 patent is held invalid or not infringed in the decision of a court.[2] Because of the paragraph IV certification, Teva's application cannot be approved by the FDA until after Ivax's 180-day exclusivity period ends. *Teva*, 395 F.3d at 1328, 1330. In other words, the running of the exclusivity period could be triggered before Ivax's first marketing date if Teva could secure a declaratory judgment of non-infringement or invalidity. Approval of Teva's ANDA would follow 180 days thereafter.

Normally, one would expect that the approval issue would be litigated between Teva and the FDA, but, as we recognized in *Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 289 F.3d 775, 778 (Fed. Cir. 2002), Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity.[3] There is certainly a concrete controversy between Pfizer (and Ivax) and Teva over when Teva's ANDA should be approved. Both Pfizer and Ivax want the approval of Teva's application delayed. Teva wants to avoid delay. The question of delay turns on infringement

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[2] To be sure, Pfizer's failure to bring suit within the 45-day period specified in section 21 U.S.C. § 355(j)(5)(B)(iii) means that the approval of the ANDA will not be delayed under that section, but despite Pfizer's failure to sue, 21 U.S.C. § 355(j)(5)(B)(iv) will bar approval until 180 days after Ivax markets the drug unless there is an earlier holding of non-infringement or invalidity.

[3] *See also Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003); *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

and validity.[4] Under these circumstances, I think there is a case or controversy within the meaning of Article III, and that the questions of infringement and validity should be addressed. The panel appears to recognize the existence of a controversy, but holds that the controversy is insufficient for purposes of Article III.[5]

I respectfully disagree. Under the panel's decision Teva lacks any remedy to contest the delay in its ANDA approval. I agree with Judge Mayer and Judge Gajarsa that Article III does not require such unfairness.

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[4] While the '518 patent imposes an additional limitation on the approval of Teva's ANDA such that it could not be approved until the '518 patent expires (June 30, 2006), it is hardly premature to litigate the approval date since litigation over infringement and invalidity of the '699 patent could itself consume a significant time.

[5] The panel states that "[t]he fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer." *Teva*, 395 F.3d at 1338.

Appendix D — 21 U.S.C. § 355(j)(5)(C)

TITLE 21. FOOD AND DRUGS

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

* * *

§ 355. New drugs

* * *

(j) Abbreviated new drug applications

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(5) * * *

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

Appendix E — 149 Cong. Rec. S15884-86 (Nov. 25, 2003)

Congressional Record — Senate
Proceedings and Debates of the 108th Congress,
First Session
Tuesday, November 25, 2003

[Page S15882]

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003—CONFERENCE REPORT

[Page S15584]

TITLE XI

Mr. KENNEDY. Mr. President, I oppose the Medicare bill before the Senate, but I want to express my understanding of the refinements of the Hatch-Waxman Act found in Title XI of the Medicare bill now before the Senate. I was deeply involved in the negotiations of these provisions in the conference. The Hatch-Waxman Act, which passed in 1984, reflects efforts by the Congress to promote two policy objectives: to encourage brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, and to enable competitors to bring cheaper, generic copies of those drugs to market as quickly as possible.

The Hatch-Waxman Act has worked very well for almost 20 years. It has provided the incentives necessary to bring the many medicines to market that have so transformed the shape of modern medical practice. And it has brought

generic drugs to market faster than ever, saving consumers billions of dollars.

As the Federal Trade Commission has shown, however, in recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the Hatch-Waxman Act found in Title XI represent refinements to the present system that will stop these abuses, will restore the original balance the law intended, and will ensure Americans more timely access to affordable pharmaceuticals. Most significantly, the Hatch-Waxman provisions in this bill limit brand-name drug companies to only one 30-month stay of approval of generic drugs. This change will stop the multiple, successive 30-month stays that the Federal Trade Commission identified as having delayed approval of generic versions of several blockbuster drugs and cost consumers billions of dollars. It also restructures how the 180-day generic exclusivity provisions work. The 180-day exclusivity gives a generic company 180 days during which it is the only generic competitor to the brand drug. The exclusivity is a very valuable incentive for generic companies. The exclusivity encourages generic companies to challenge patents that are likely invalid or not infringed and, because it goes to the first generic applicant to challenge a brand-name drug patent, it encourages challenges of those patents as soon as possible. These incentives mean that consumers will be able to enjoy the lower prices provided by generic companies sooner rather than later.

The Federal Trade Commission reports that the exclusivity has at times been parked through collusive agreements between brand and generic companies. Parking the exclusivity has blocked other generic companies from getting to market and has cost consumers billions of dollars.

The Hatch-Waxman provisions in this bill are intended to prevent parking of the exclusivity. It does this by providing for several situations in which a generic company with the exclusivity forfeits the exclusivity, clearing the way for other generic companies to bring their products to market.

The Hatch-Waxman provisions in this bill also make the exclusivity available only with respect to the patent or patents challenged on the first day generic applicants challenge brand drug patents, which makes the exclusivity a product-by-product exclusivity rather than a patent-by-patent exclusivity, and the exclusivity is available to more than one generic applicant, if they all challenge patents on the same day.

Mr. SCHUMER. Mr. President, will the Senator yield for a question?

Mr. KENNEDY. Yes, I will yield to my friend from New York.

Mr. SCHUMER. Thank you, Mr. President. Let my just say, before I ask my question, that I want to thank the Senator from Massachusetts, and the senior Senator from New Hampshire, for their leadership on this issue. The

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Senator from Massachusetts, as chair of the HELP Committee last year, took up the generic drug bill authored by the senior Senator from Arizona and myself, saw it through the HELP Committee, and managed its passage by the full Senate. This year, the senior Senator from New Hampshire approached me to work together to come up with the generic drug bill that served as the basis for what is in

this bill, and he brought it through the HELP Committee, offered it as an amendment to the prescription drug bill in the Senate, where it was accepted 94-1, and defended it very ably in conference with the House. So, again, I would like to thank both distinguished chair and ranking member of the HELP Committee for their leadership on this issue.

Of course, I also want to thank the senior Senator from Arizona, without whose leadership over the past several years we would not be where we are today on such an important consumer issue.

As for my question, I understand that a generic applicant that has the 180- day exclusivity will forfeit the exclusivity if it has failed to market its product 75 days after certain events have happened with respect to itself or another generic applicant and with respect to each of the patents that gives the generic applicant its generic exclusivity. Is that correct?

Mr. KENNEDY. That is correct.

Mr. SCHUMER. And am I correct that one of these events is when "a court enters a final decision" that the patent is invalid or not infringed by the drug of the generic applicant?

Mr. KENNEDY. The Senator is correct.

Mr. SCHUMER. And am I correct that a final court decision under this provision includes the kind of court decision recognized in the Teva v. Shalala opinion?

Mr. KENNEDY. Yes, I very much appreciate your question on this point. We do intend that a court decision like

the one in the D.C. Circuit's 1999 decision in Teva v. Shalala-a decision dismissing a declaratory judgment action for lack of subject matter jurisdiction because the patent owner has represented that the patent is not infringed-will count as a court decision under the new "failure to market" provision. Under the failure to market provision, the conditions for forfeiture are intended to be satisfied when a generic company has resolved patent disputes on all the patents that earned the first-to-file its exclusivity. After a court decision such as that at issue in Teva v. Shalala, the patent owner is estopped from suing the generic applicant in the future and the patent dispute is resolved. So these sorts of decisions should be recognized as court decisions under the failure to market provision.

I'd also like to point out the importance of the declaratory judgment provisions that are in the Senate bill and are retained in modified form by the conferees in the conference report now before the Senate. Amendments made by this bill to both the Federal Food, Drug, and Cosmetic Act and Title 35 clarify that generic applicants may bring declaratory judgment acts to ensure timely resolution of patent disputes. These provisions authorize a generic applicant to bring a declaratory judgment action to obtain a judicial determination that a listed patent is invalid or is not infringed if the applicant is not sued within 45 days of having given notice to the patent owner and brand-name drug company that it is challenging the patent. This clarification of a generic applicants right to bring a declaratory judgment action is crucial to ensuring prompt resolution of patent issues, which is essential to achieve our goal of speeding generic drugs to market.

It's worth pointing out that the Hatch-Waxman Act has always provided that patent owners and brand drug

companies can bring patent infringement suits against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent. The declaratory judgment provisions in Title XI of this bill simply level the playing field by making it clear that the generic applicant can also seek a prompt resolution of these patent issues by bringing a declaratory judgment action if neither the patent owner nor the brand drug company brings such a suit within 45 days after receiving notice of the patent challenge.

Mr. McCAIN. Mr. President, will the Senator yield for a question?

Mr. KENNEDY. Yes, I will yield.

Mr. McCAIN. Will the Senator please explain for me and our colleagues the purpose of the provision in Title XI that amends Title 35 to say that courts must hear declaratory judgment actions brought by generic applicants?

Mr. KENNEDY. Certainly. The provision in Title 35 is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe. The mere fact that neither

the patent owner nor the brand drug company has brought a patent infringement suit within 45 days against a generic applicant does not mean there is no "case or controversy." The sole purpose of requiring the passage of 45 days is to provide the patent owner and brand-name drug company the first opportunity to begin patent litigation. Inaction within the 45-day period proves nothing, as there are tactical reasons why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days.

For example, the brand drug company might have several patents listed in the Food and Drug Administration's Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve. The suit on one patent would automatically stay approval of the generic application until the lawsuit is resolved or the 30 months elapses. Holding the other patents in reserve would introduce uncertainty that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement suit.

Or for patents on which no 30-month stay is available, the brand drug company could sit back to create uncertainty and similarly delay generic entry by delaying resolution of those patents. Or when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

In each of these and in other circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45- day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

Mr. McCAIN. Mr. President, will the distinguished Senator yield?

Mr. KENNEDY. Yes, I will yield.

Mr. McCAIN. Mr. President, I'd like to ask the Senator if it is the intent of this legislation that the declaratory judgment provisions in this bill, in particular, the change to Title 35, will be available immediately to help generic drug applicants who are now in federal court seeking declaratory judgments that listed drug patents are invalid or are not infringed by their product?

Mr. KENNEDY. I agree with the distinguished Senator from Arizona. It is clearly our intent that, under these

[Page S15886]

provisions, courts considering jurisdictional challenges to declaratory judgment actions brought by generic drug companies should apply the standards set forth in this bill to such challenges in any case pending (either in the trial court or on appeal) at the time of enactment in order to resolve

patent issues as soon as possible and to clear the way for quicker generic entry.

Mr. McCAIN. I thank the Senator for his answer and for his leadership on these issues. His experience and technical expertise have been invaluable. I would also like to thank my friend, the senior Senator from New York, who has worked with me these many years on this legislation. His dedication to American consumers and his commitment to restoring fairness to the drug industry must be commended. The senior Senator from New Hampshire must also be recognized for leadership on this issue in his committee, in the Senate, and in the conference on this bill. I would also like to thank the staffs of all three of these Senators, who have worked tirelessly on behalf of this issue. I ask unanimous consent that a letter from Chairman Muris of the Federal Trade Commission about the value of the declaratory judgment provision in Title 35 be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

FEDERAL TRADE COMMISSION,
Washington, DC, October 21, 2003.

Hon. JUDD GREGG,
Hon. EDWARD M. KENNEDY,
Senate Committee on Health, Education, Labor, and Pensions, Washington, DC.

DEAR CHAIRMAN GREGG AND RANKING MEMBER KENNEDY: In written testimony submitted to the Senate Judiciary Committee on August 1, 2003, for a hearing entitled, "Examining the Senate and House Versions of the 'Greater Access to Affordable Pharmaceuticals Act,'" the

Federal Trade Commission commented on both the Senate and House-passed bills that reform the Hatch-Waxman generic drug approval process. The reforms are nearly identical to recommendations contained in the FTC's July 2002 study entitled, "Generic Drug Entry Prior to Patent Expiration."

I understand that one particular provision contained in the Senate-passed version is of particular interest now on the bills proceed through the conference process. Specifically, the Senate bill adds a provision clarifying that if a brand-name company fails to bring an infringement action within 45 days of receiving notice of an abbreviated new drug application (ANDA) containing a paragraph IV certification, the generic applicant can bring a declaratory judgment action that the patent is invalid or not infringed. Without commenting on the provision's constitutionality, the Commission has stated that "the Senate provision may help ensure that a federal court has subject matter jurisdiction to resolve the patent issues." While I defer to others as to the constitutionality of the Senate provision, I note that a court's dismissal of a declaratory judgment action for lack of controversy may resolve uncertainty concerning whether a generic product infringes a brand-name company's patent. It also can reduce the incentives for the brand-name company and the first generic applicant to park the 180-day exclusivity. Without the right to seek a declaratory judgment, a subsequent generic applicant that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because the subsequent generic applicant will not be sued for patent infringement by the brand-name company. If the brand-name company and the first generic applicant agree that the generic will not begin commercial marketing, then the 180-day exclusivity becomes an absolute bar to any general entrant. Moreover, speedier resolution of patent

infringement suits will redound to the benefit of consumers by resolving any possible uncertainty that prevents a generic applicant from marketing its products. If also will allow for the simultaneous running of the periods for FDA approval and for the resolutions of patent infringement issues.

For these reasons, I believes the declaratory judgment provision in the Senate-passed bill would be a useful mechanism to reduce uncertainty in the Hatch-Waxman process and potentially could speed access of generic drugs to consumers.

Sincerely,
TIMOTHY J. MURIS.

Appendix F — H.R. Conf. Rep. No. 108-391, at 836 (2003)

HOUSE OF REPRESENTATIVES
108TH CONGRESS
1st Session

Report 108-391

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

CONFERENCE REPORT
to accompany
H.R. 1

NOVEMBER 21 (legislative day, NOVEMBER 20), 2003—
Ordered to be printed

[Page 832]

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

[Page 835]

Provisions Related to Hatch-Waxman Law

[Page 836]

DECLARATORY JUDGMENTS

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers

and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable apprehension" of suit to establish jurisdiction. See, e.g., *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002). In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

SEP 7 - 2005

(2)

No. 05- 48

IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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September 7, 2005

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTION PRESENTED

Whether the court below properly determined, on the particular factual record of this declaratory-judgment action, that there was not a ripe Article III case or controversy for it to adjudicate, particularly given that the declaratory-judgment plaintiff did not intend to market the potentially infringing product in question for years, if ever, and given that the plaintiff acknowledged that the declaratory-judgment defendant had no current interest in asserting its patent rights against the plaintiff.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of this Court's rules, respondent Pfizer Inc. ("Pfizer"), designated "Pfizer, Inc." in the caption, states that it has no parent and no publicly held company owns 10% or more of its stock.

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RESPONDENT'S BRIEF IN OPPOSITION

STATEMENT OF THE CASE

In this action, Petitioner Teva Pharmaceuticals USA, Inc. ("Teva") seeks an advisory opinion on whether a generic pharmaceutical that it may someday attempt to market, but for which it concededly will not seek FDA approval until at least July 2006, infringes a patent that Teva itself alleges respondent Pfizer has no present interest in asserting against Teva. Affirming the district court, the Federal Circuit properly declined the invitation to embark on such a hypothetical, speculative inquiry in light of the Article III requirement of an actual and concrete "Case[]" or "Controvers[y]." Such a routine justiciability determination, based on the specific factual circumstances of this case, and involving a statutory scheme that has since been amended to alter the analysis fundamentally in future cases, does not warrant this Court's review.

A. The Statutory Scheme Governing Expedited FDA Approval of Generic Pharmaceuticals.

1. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, manufacturers of both innovative and generic pharmaceuticals must follow procedures for Food and Drug Administration ("FDA") approval of a drug, which include the filing of a New Drug Application ("NDA"). *Id.* § 355(a). In the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282), (commonly referred to as the Hatch-Waxman statute), however, Congress alternatively provided for special, expedited procedures for the introduction of generic pharmaceuticals into the marketplace. Reflecting a balance between the policies of creating incentives for innovating new pharmaceuticals and

allowing the prompt introduction of less-expensive generic products into the marketplace, the expedited Hatch-Waxman procedures allow manufacturers of generic pharmaceuticals that are identical and bioequivalent to drugs previously approved by the FDA to obtain approval by filing an Abbreviated New Drug Application ("ANDA"), rather than a full NDA. 21 U.S.C. § 355(j).

The process for approval of such a tag-along ANDA application builds off of the filing of the earlier, completed NDA for a new pharmaceutical product. In conjunction with its NDA filing, the NDA applicant must supply to the FDA a list of all patents "claim[ing] the drug for which the applicant submitted the application" and "with respect to which a claim of patent infringement could reasonably be asserted." *Id.* § 355(b)(1); *see also id.* § 355(c)(2). The FDA publishes these patent listings in an appendix to the "Orange Book," *Approved Drug Products With Therapeutic Equivalence Evaluations*, *available at* http://www.fda.gov/-cder/ob/default.htm (last visited Sept. 1, 2005).

An ANDA filer for FDA approval may, upon demonstrating the identity and bioequivalence of its product with the prior NDA product, rely upon the earlier drug's safety and efficacy studies. 21 U.S.C. § 355(j)(2)(A); Pet. App. 4a. Accompanying such an ANDA filing, a generic applicant must make one of four possible certifications with respect to every patent listed in the Orange Book under the NDA on which the ANDA is premised. A "paragraph I" certification states that required patent information was not filed by the NDA holder with the FDA. A "paragraph II" certification indicates that the patent in question has expired. A "paragraph III" certification states that the patent will expire on a particular date in the future, in which case the FDA cannot approve the ANDA until after that expiration date has passed. And a "paragraph IV" certification states that "the patent is invalid or will not be infringed by . . . the new drug." *Id.* § 355(j)(2)(A)(vii)(I-IV).

Under the Hatch-Waxman Act, while steps necessary to prepare an ANDA do not constitute infringement of an Orange Book patent (even if those acts might otherwise be infringing), the actual filing of an ANDA containing a paragraph IV certification is deemed a statutory act of patent infringement. 35 U.S.C. § 271(e)(2). Moreover, an applicant's filing of an ANDA incorporating a paragraph IV certification starts a 45-day period during which the patentee may sue the ANDA applicant for this statutory infringement, and during which the ANDA applicant may not bring a declaratory-judgment action with regard to the patent that was the subject of the certification. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues for infringement during this period, the FDA may not approve the ANDA for thirty months, unless the lawsuit is resolved in favor of the ANDA applicant. *Id.* If the 45-day period expires without the patentee bringing suit, the FDA may approve the ANDA. *Id.*

Under the statute, the first ANDA applicant to file a paragraph IV certification receives the benefit of a 180-day exclusivity period during which the FDA may not approve any other paragraph IV ANDAs based upon the same NDA. *Id.* § 355(j)(5)(B)(iv). Under the statutory regime applicable to this case (but that has since been amended, as discussed below), the 180-day exclusivity period began to run upon the earlier of two events: The date when the ANDA product is first commercially marketed, or "the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed." *Id.* § 355(j)(5)(B)(iv).

2. In 2003, however, Congress amended this statutory scheme in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"). The Medicare Amendments make several pertinent changes to the ANDA approval process.

Most significantly, the Medicare Amendments revise the provisions governing the 180-day exclusivity period for a first ANDA filer in all ANDAs filed after December 8, 2003. The new provisions change the statute so that, rather than have a court-decision alternative as a possible means to begin the 180-day exclusivity period, the 180-day exclusivity period begins to run only on the date of first commercial marketing, 21 U.S.C. § 355(j)(5)(B)(iv), subject to a forfeiture of the exclusivity under six circumstances: (1) if the first applicant fails timely to market the pharmaceutical; (2) if the first applicant withdraws its ANDA; (3) if the first applicant withdraws its paragraph IV certification; (4) if the first applicant fails to obtain tentative approval within specified time periods; (5) if the first applicant enters into an agreement found by the Federal Trade Commission ("FTC") or a court to violate the antitrust laws; or (6) if all patents subject to paragraph IV certifications expire. *Id.* § 505(j)(5)(D). Thus, while a court judgment of invalidity or non-infringement can factor into the exclusivity analysis, it does so only in an entirely different way from the pre-2003 regime at issue in this case — specifically, only as a subsidiary component of the "failure to market" forfeiture analysis. *Id.* § 355(j)(5)(D)(i)(I)(aa). These new criteria for starting the 180 days and the forfeiture provisions (with the exception of the collusive agreement forfeiture provision, which is not at issue here) apply only prospectively to ANDAs filed after December 8, 2003, and thus do not apply to this case. Pet. App. 6a-7a & n.3.

The Medicare Amendments also impose a new requirement upon ANDA applicants who file declaratory-judgment actions regarding Orange Book patents after the expiration of the 45-day period. Specifically, they require that such ANDA applicants offer confidential access to the ANDA materials to allow the patentee or NDA holder to evaluate issues pertaining to infringement. 21 U.S.C. § 355(j)(5)(C) (Supp. 2004). The Medicare Amendments also state that, after the 45-day period, "courts of the United

States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought . . . under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (Supp. 2004).

B. The FDA's Approval of Zoloft®, The Subsequent ANDAs, And The Litigation Below

1. Pfizer manufactures and sells Zoloft®, a pharmaceutical for treating certain mood and anxiety disorders. The active ingredient in Zoloft® is sertraline hydrochloride, which acts by inhibiting the uptake of serotonin in the brain. In obtaining its NDA for this compound, Pfizer filed with the FDA a listing of patents covering Zoloft® or a method of use for Zoloft®, and the FDA published these patents in the Orange Book. Among these patents are United States Patent No. 4,356,518 (the "'518 patent"), which claims the compound sertraline hydrochloride, and United States Patent No. 5,248,699 (the "'699 patent"), which claims a particular polymorphic form of sertraline hydrochloride.

In 1999, the predecessor to Ivax Pharmaceuticals, Inc. ("Ivax") notified Pfizer that it had filed an ANDA seeking FDA approval to market generic sertraline hydrochloride tablets. In that ANDA, Ivax filed a paragraph III certification with regard to the '518 patent, and thus sought approval for its generic product only beginning after the expiration of that patent, which (as adjusted by the FDA for six months due to Pfizer's performance of requested pediatric studies) will not occur until June 30, 2006. Ivax also filed a paragraph IV certification (claiming invalidity or non-infringement) with regard to the '699 patent. This latter patent will not expire until September 29, 2010, but Ivax's paragraph IV certification meant Ivax was seeking approval before that second patent expires.

Because Ivax was the first generic manufacturer to file a paragraph IV certification, no subsequent generic applicants can obtain approval for their ANDAs until the expiration of the 180-day period provided by the statute. Under the pre-2003 Hatch-Waxman regime applicable at that time, the 180-day "exclusivity" period would commence from the earlier of Ivax's first commercial marketing of its generic product or a final, non-appealable court decision of non-infringement or invalidity with respect to the '699 patent. 21 U.S.C. § 355(j)(5)(B)(iv).

Within forty-five days after receipt of Ivax's notice, Pfizer sued Ivax, *inter alia*, for infringing the '699 patent. In May 2002, Pfizer and Ivax settled the action. In doing so, Pfizer granted Ivax a license to the '699 patent upon approval of Ivax's generic product by the FDA after the '518 patent (with pediatric exclusivity) expires on June 30, 2006.

In July 2002, after Pfizer and Ivax had settled Pfizer's infringement lawsuit, Teva filed an ANDA seeking approval to market generic sertraline hydrochloride tablets. Like Ivax, Teva filed a paragraph III certification with respect to the '518 patent, thereby delaying any request for FDA approval until after June 30, 2006, and a paragraph IV certification with regard to the '699 patent. Pfizer did not bring suit against Teva within forty-five days after receiving its ANDA notice, and made no threats of suit or otherwise engaged in any conduct indicating that it might sue Teva. Consequently, the '699 patent is not an obstacle to the FDA's approval of Teva's ANDA, which the FDA can approve immediately after the expiration of the period created by Teva's own paragraph III certification and the expiration of the 180-day exclusivity period enjoyed by Ivax for being the first paragraph IV filer. 21 U.S.C. § 355(j)(5)(B)(ii), (iv).

2. On January 24, 2003, Teva sued Pfizer, seeking a declaratory judgment that Teva's proposed generic product would not infringe the '699 patent and that claims of the

'699 patent were invalid. Pfizer moved to dismiss the complaint for lack of subject matter jurisdiction and, on December 8, 2003, the district court granted Pfizer's motion.

The district court noted that there is jurisdiction under the Declaratory Judgment Act only where there is some "actual controversy" between the parties. Pet. App. 43a (internal quotation marks omitted). Applying a test previously announced by the Federal Circuit for examining the presence of a constitutional case or controversy in the patent context, the district court found that there must be some "present activity which could constitute infringement," and also "an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit." Pet. App. 43a (internal quotation marks omitted).

Finding the first requirement satisfied, *id.*, the district court nonetheless found that there was no conduct by Pfizer creating any reasonable apprehension of an infringement suit. It noted that there need not be any "express charge of infringement" to satisfy this requirement, but found that there must be some conduct "indicat[ing] an intent on the part of the patentee to enforce its patent." Pet. App. 44a (internal quotation marks and brackets omitted). The district court concluded that neither Pfizer's mere listing of the '699 patent in the Orange Book, nor Pfizer's failure to commit *not* to sue Teva, nor Pfizer's previous record of enforcing patents against others, created any reasonable apprehension on the part of Teva that Pfizer would sue Teva to enforce the '699 patent. Pet. App. 44a-46a.

3. The Federal Circuit affirmed by a 2-1 vote. Judge Mayer dissented.

a. While noting that it was not the exclusive test of a "case" or "controversy," Pet. App. 20a, the panel majority applied the "two-part inquiry" requiring both present infringing activity and facts supporting "a reasonable

apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." Pet App. 13a. Evaluating "the totality of the circumstances," Pet. App. 15a (internal quotation marks omitted); *see also* Pet. App. 12a (considering "all the circumstances" of the case at hand (internal quotation marks omitted)), the panel majority found no case or controversy supporting Teva's declaratory-judgment action.

The panel majority concluded that "Teva's reliance on Pfizer's listing of the '699 patent in the Orange Book is misplaced," because this statutory obligation merely lists "patents with respect to which claims of infringement '*could* be reasonably asserted . . . .' 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however." Pet. App. 15a.

The panel majority also found insufficient "Pfizer's history of defending its patents and its refusal to grant Teva a covenant not to sue." Pet. App. 15a. While finding these considerations to be "relevant to the analysis," *id.*, it determined that neither proved "dispositive in this case." Pet. App. 16a. The panel majority noted that "[a]ccording to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringement or invalidity determination," and thus was "unable to demonstrate a reasonable apprehension of imminent suit on the part of Pfizer for infringement of the '699 patent." Pet. App. 16a-17a.

The panel majority also rejected Teva's argument that the express provision for a declaratory judgment action after the 45-day period in the Medicare Amendments altered the outcome. The panel majority noted that the plain language of the revised section 271(e)(5) (Supp. 2004) stipulates that jurisdiction must be "consistent with the Constitution," thus acknowledging the governing case or controversy requirements. Pet. App. 18a, 21a. Because it found that the

parties' "adverse interests have not ripened into an actual controversy," Pet. App. 21a, the panel majority found that the statutory and constitutional standard for jurisdiction was not satisfied. The panel also reviewed the legislative history of the Medicare Amendments and determined that Congress had both rejected a proposal for declaratory judgment actions with more categorical language and embraced the "reasonable apprehension" standard in the conference report. Pet. App. 21a-24a. The panel concluded that "[i]f it is the view of Congress that the 180-day exclusivity period for a first ANDA filer creates inequities, it can amend the Hatch-Waxman Amendments accordingly." Pet. App. 26a.

b. In dissent, Judge Mayer did not reject the reasonable apprehension standard. Rather, he argued that "the filing of a[n NDA] and subsequent listing of a pharmaceutical patent in the [Orange Book] is conduct giving rise to a reasonable apprehension that an [ANDA] filer and declaratory judgment plaintiff will face a patent infringement suit." Pet. App. 27a.

c. By a 9-3 vote, the Federal Circuit denied Teva's petition for *en banc* review of the case. Pet. App. 49a. Judge Gajarsa wrote to express the view that the case should be analyzed under the three-part test for standing (requiring "concrete, actual or imminent injury in fact," causation, and redressability) announced in cases like *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83 (1998). Pet. App. 52a. Judge Dyk also wrote a dissent from the denial, though he agreed with the panel majority that there was no present controversy sufficient to satisfy Article III regarding Teva's infringement of the '699 patent, simply because Pfizer did not object to Teva's ANDA filing. Pet. App. 64a. Nor did Judge Dyk find any justiciable controversy over "whether Teva should be allowed to manufacture and market the drug without incurring damages for infringement," because "Teva has not alleged that it intends to market or sell the drug at any time in the near future or that it is being prevented from

doing so by the risk of infringement damages." *Id.* Nonetheless, Judge Dyk believed that there was a justiciable controversy "over whether Teva's ANDA should be approved earlier than 180 days after Ivax commences marketing," *id.*, even though he acknowledged that "[n]ormally, one would expect that the approval issue would be litigated between Teva and the FDA." Pet. App. 65a.

4. Teva filed the present petition for certiorari on July 5, 2005. Twenty days later, Teva and Ivax jointly announced "a definitive agreement providing for the acquisition of IVAX by TEVA," under which Ivax will become a Teva subsidiary. http://www.tevapharm.com/pr/2005/pr_536.asp (last accessed Sept. 1, 2005). Teva and Ivax announced that "[t]he transaction is expected to close in late 2005 or early 2006." The completion of that transaction would eliminate any incentive for Teva to pursue approval for the ANDA it filed, because Teva would have no interest in competing with its own subsidiary's generic product, or in shortening its own 180-day exclusivity period. Thus, the basis of Teva's claimed controversy, its alleged inability to cause Ivax's 180-day exclusivity period to start running through a court judgment of invalidity or non-infringement, will almost certainly never ripen into any actual dispute in light of its acquisition of Ivax.

REASONS FOR DENYING THE PETITION

The petition for a writ of certiorari should be denied. It raises no important or recurring issue warranting this Court's review; on the contrary, the decision below is entirely fact-bound, and because of amendments to the key provisions of the statute, even the concern expressed by Teva and the dissenting judges below has been abrogated by amendments to the operative ANDA regime. Further, the decision below is entirely consistent with this Court's decisions and the decisions of other courts; contrary to the petition, the decision below does not create any circuit split. Finally, the

decision below is correct on the merits; the petition's contrary argument rests on a misstatement of both the applicable law and the grounds for the decision below. The correctness of the panel's decision is underscored by Teva's announced acquisition of Ivax, which not only confirms that there is no ripe dispute, but shows that it is unlikely there ever will be a mature dispute over the issue raised in the petition.

I. THE PETITION RAISES NO IMPORTANT OR RECURRING ISSUE WARRANTING THIS COURT'S REVIEW.

At the outset, it should be emphasized that the petition raises no important or recurring issue that could possibly warrant this Court's review. Under this Court's rules, the Court will expend its limited resources to review a case only where there are "compelling reasons" for doing so, including "important question[s] of federal law." Supreme Court Rule 10, 10(c). This requirement of importance of an issue is not satisfied, and a case is unsuitable for review by this Court, where the issue raised in the petition is unlikely to recur outside the case immediately under review. For example, it has been explained that, where intervening amendments to a statutory scheme diminish the likelihood of recurrence of the issue raised in a certiorari petition, an issue is not worthy of review. *See, e.g.*, John M. Harlan, *Some Aspects of the Judicial Process in the Supreme Court of the United States*, 33 AUSTRALIAN L.J. 108 (1959) (noting vehicle problems precluding review where the issue "is not apt to have continuing legal consequences, as where a statute which has given rise to conflicting interpretations has been repealed or amended"). Similarly, where an issue is narrowly fact-bound, it is not an appropriate candidate for review by this Court. *See, e.g.*, *Rice v. Sioux City Mem'l Park Cemetary*, 349 U.S. 70, 74 (1955) (noting that issue should be "beyond the academic or the episodic"). For both of these reasons, the petition here does not warrant review.

First, intervening statutory amendments have fundamentally altered the relevant statutory analysis. They have replaced the procedures governing the exclusivity period in cases involving ANDAs filed after December 8, 2003.

The petition claims that the Pfizer/Ivax settlement created an incentive for Pfizer not to initiate litigation against subsequent ANDA applicants filing paragraph IV certifications, because doing so could theoretically lead to an "adverse court judgment" that, under the extant statutory regime, would cause the exclusivity period to begin running before Ivax began to market its generic pharmaceutical. The petition asserts that there is a "financial incentive to *delay* the commencement of infringement litigation," Pet. 19, in order to avoid accelerating the 180-day exclusivity period awarded to the first generic applicant. The petition argues that, "[u]nless Teva can obtain a judicial determination whether its generic version of Zoloft[®] infringes Pfizer's patent, it cannot trigger IVAX's exclusivity and thereby avoid delaying the launch of its generic product until at least six months after the ['518] patent expires." Pet. 23. This was the issue that concerned the panel and en banc dissenters in the Federal Circuit. *See* Pet. App. 33a-34a (Mayer, J., dissenting) (claiming a "cognizable injury" based upon "brand-name firm[s] forego[ing] suing subsequent ANDA applicants" to avoid starting the 180-day period); Pet. App. 55a (Gajarsa, J., dissenting) (claiming that Pfizer "insulated itself from any judicial determination" during the 180-day period); Pet. App. 65a (Dyk, J., dissenting) (finding a controversy because "Congress provided that approval would depend on the outcome of litigation between private parties (the patent owner and the potential infringer) over the questions of infringement and validity").

That concern will not arise, however, in future cases in light of the recent Medicare Amendments. As explained above (*supra* at 4), the Medicare Amendments replaced the

alternative "court decision" means of starting the 180-day period running with several exclusivity "forfeiture" provisions, under which a court decision regarding infringement or validity plays an entirely different and substantially more limited role. Indeed, under the Medicare Amendments, an ANDA applicant must have "received tentative approval" for its generic drug in order for an adverse court judgment to enter the analysis at all. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Therefore, a party in Teva's position (*i.e.*, a party who like Teva has never received tentative approval for its generic drug) could not make use of any court judgment of invalidity or non-infringement to cause forfeiture of the exclusivity period even if it obtained such a judgment. In other words, as amended, the statute no longer incorporates a simple "adverse judgment" starting point like the one at issue in this case, and the concerns asserted by the petition and the dissents below do not even apply to future cases of this type under the amended statute. In these circumstances, where the operative provision of the statute at issue "has been . . . amended" in a way that will radically alter the issue in future cases and prevent it from arising at all in cases like this one, certiorari review is not appropriate, because the issue raised in the petition "is not apt to have continuing legal consequences." Harlan, *supra*, 33 AUSTRALIAN L.J. at 108.

Second, even under the pre-amendments statutory regime applicable to this case, the petition raises no issue of general significance, because it arises only in a narrowly fact-intensive posture. Contrary to the petition, the court below did not purport to pronounce any new rule of justiciability, much less a rule of sweeping application. Rather, the court applied a longstanding test for justiciability, Pet. App. 13a, indicated that it did not view that test as the only test of justiciability, Pet. App. 20a, and made clear that its application of that test was limited to the particular "totality of the circumstances" in the present case, Pet. App. 15a (internal quotation marks omitted); *accord* Pet. App. 12a.

Such a decision is plainly not important enough to merit this Court's review.

Specifically, the question in this case arises in, and rests on, a quite unusual combination of independent predicate facts:

- The patentee must have two or more Orange Book patents relating to the NDA product in question.
- These patents must expire at significantly different times.
- There must be at least two prospective generic entrants into the market.
- The prospective generic entrants must file paragraph III certifications with respect to the earlier-expiring patent — thus deferring the onset of both the exclusivity period and the second entrant's attempt to market its generic product — and they must also make paragraph IV certifications with respect to the later-expiring patent.
- The patentee must settle the dispute over the later-expiring patent with the first generic entrant on terms granting it a license.
- The second generic entrant must have no intent to market its product for several years.
- The patentee must exhibit no conduct indicating any intention of suing the second generic entrant for infringement based upon its ANDA filing.

It was on these specific and unique facts that the court below held that, in the "totality of the circumstances," Pet. App. 15a (internal quotation marks omitted), no ripe case or controversy existed for adjudication. The Federal Circuit expressly disclaimed reliance on any categorical rules and instead looked to the totality of the evidence to determine whether there existed a controversy of sufficient immediacy to satisfy the justiciability requirements of Article III. The

panel acknowledged, for example, that "the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met." Pet. App. 20a. And it found the facts relied upon by Teva to be "relevant" to the analysis, but not "dispositive" in the case at hand. Pet. App. 15a-16a. Noting that Teva had no intent to market its product for several years, Pet. App. 16a ("Teva will not be able to receive FDA approval for its generic sertraline drug prior to the expiration of Ivax's 180-day exclusivity period, which will not begin until expiration of the '518 patent on June 30, 2006."), and that Pfizer has shown no intent to enforce its patent rights before that time, Pet. 16a, the panel majority concluded that the parties' "adverse interests have not ripened into an actual controversy," Pet. App. 21a.

In short, the decision below announced no broad or new principle of law and rested upon a fact-bound evaluation of the unusual record in this case. Accordingly, the decision below does not rise "beyond the academic or the episodic," and does not warrant consuming this Court's limited resources to review. *Rice*, 349 U.S. at 74.

II. THE DECISION BELOW IS CONSISTENT WITH THIS COURT'S DECISIONS AND CREATES NO SPLIT AMONG THE CIRCUITS.

Nor is review warranted to resolve any conflict between the decision below and either the decisions of this Court or the decisions of other courts of appeals. The petition errs in suggesting that any such conflict exists. Pet. 20-25.

1. The Federal Circuit's reliance on and application of the "reasonable apprehension" standard is fully supported by this Court's cases. That standard distinguishes ripe, justiciable declaratory-judgment actions from those that are not ripe and immediate.

a. As this Court has long held, in order to present a ripe, justiciable controversy, a declaratory judgment action "must be definite and concrete, touching the legal relations of parties having adverse legal interests," not merely "of a hypothetical or abstract character." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). Specifically, the Court has held that a declaratory-judgment dispute must have "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *accord, e.g., Lake Carriers' Ass'n v. MacMullen*, 406 U.S. 498, 508 (1972).

Applying that standard, this Court has routinely held nonjusticiable declaratory-judgment actions that fail the requirements of ripeness and immediacy. For example, in *Texas v. United States*, 523 U.S. 296 (1998), the Court unanimously rejected as unripe a declaratory judgment action brought by a State to determine whether a potential future action authorized by a State statute under certain circumstances that were not yet present would trigger the preclearance provisions of the Voting Rights Act. *See id.* at 300 ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (internal quotation marks omitted)). And, in *Textron Lycoming Reciprocating Engine Division, Avco Corp. v. United Automobile, Aerospace & Agricultural Implement Workers of America*, 523 U.S. 653 (1998), the Court found no Article III controversy sufficiently ripe to support a union's declaratory-judgment action to determine the validity of a collective-bargaining agreement, because there was "no indication that [the employer] had any interest in defending the binding nature of the contract." *Id.* at 661. *See also Ashcroft v. Mattis*, 431 U.S. 171, 172-73 & n.2 (1977) (per curiam) (finding no "present, live controversy" supporting a declaratory judgment based upon "speculation" about potential future legal adversity); *Laird v. Tatum*, 408 U.S. 1, 10 (1972) (rejecting justiciability of declaratory judgment action based

upon allegation "that the exercise of his First Amendment rights is being chilled by the mere existence, without more, of a governmental investigative and data-gathering activity").

The immediacy requirement has led to more specific ripeness tests in particular contexts. Of particular importance here, for example, the Court has made it clear that constitutional challenges to statutes fail to satisfy the case or controversy requirement unless there is an imminent threat of prosecution under the statue. Thus, in *Boyle v. Landry*, 401 U.S. 77 (1971), the Court rejected constitutional challenges to State laws because there was no "specific threat by any officer or official . . . to arrest or prosecute" the plaintiffs. *Id.* at 81. In the absence of any such concrete threat, any judicial resolution would involve improper "speculation about the future." *Id. See also Elec. Bond & Share Co. v. Secs. & Exch. Comm'n*, 303 U.S. 419, 443 (1938) (refusing to offer "an advisory decree upon a hypothetical state of facts" in a declaratory challenge to provisions of a regulatory statute not under threat of actual prosecution); 10B Charles Alan Wright, *et al.*, *Federal Practice and Procedure* § 2757, at 477-84 (3d ed. 1998) (noting that "courts have declined to hear cases seeking a declaratory judgment on the constitutionality of a particular statute or ordinance when plaintiff has not shown that there is any immediate threat that the statute will be enforced against him").

The Federal Circuit's "reasonable apprehension" test is a well-established application of the imminent threat of prosecution standard. It applies that standard, and more generally adapts the immediacy requirement, to the context of declaratory judgments over patent infringement and validity issues. Paralleling the requirement of an actual threat of prosecution in the statutory context, the "reasonable apprehension" test requires some threat or conduct by the patentee "which creates a reasonable apprehension on the

part of the declaratory judgment plaintiff that it will face an infringement suit." Pet. App. 13a. In short, the "reasonable apprehension" test flows naturally from this Court's cases, and plainly is not in conflict with them.

b. Teva claims that the *Aetna Life Insurance* case conflicts with the "reasonable apprehension" standard because "there is no hint in the Court's opinion that the insurer faced any threat of imminent litigation." Pet. 21-22. To the contrary, the declaratory judgment defendant in that case, an insured, had taken concrete steps to put the plaintiff insurance company on reasonable notice of an adverse legal position, and had created a reasonable apprehension of imminent suit. *See* 300 U.S. at 237. Indeed, the insured had not only affirmatively "claimed the disability benefits" in question, but had "repeatedly renewed" those claims. *Id.* And, in finding a controversy that was ripe for resolution, the Court relied on those facts, finding that the dispute was not "hypothetical or abstract," but was ripe and immediate, *id.* at 240, because, "[p]rior to this suit, the parties had taken adverse positions with respect to their existing obligations," *id.* at 242. Indeed, *Aetna Life Insurance* is routinely cited in this Court's cases for its recognition and application of the immediacy requirement. *See, e.g.*, *Md. Cas. Co.*, 312 U.S. at 273.

The petition, like Judge Gajarsa below, Pet. App. 52a, also claims that the decision below conflicts with several cases discussing the requirements for Article III standing. Pet. 21-22 (citing *Bennett v. Spear*, 520 U.S. 154 (1997), and *ASARCO, Inc. v. Kadish*, 490 U.S. 605 (1989)). But these two cases address only the requirements for standing, because it was the only justiciability requirement at issue in them. *See Bennett*, 520 U.S. at 160; *ASARCO*, 490 U.S. at 613. Nothing in these cases purports to displace this Court's other cases holding that, in addition to standing, ripeness is also a prerequisite for justiciability. *See, e.g.*, *Allen v. Wright*, 468 U.S. 737, 750 (1984) (noting that justiciability

involves "not only standing but mootness, ripeness, political question, and the like" (internal quotation marks omitted)); *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975) (discussing relationships among standing, ripeness, and mootness requirements).

2. The decision below is also entirely consistent with the law in other circuits. The petition relies primarily on *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), *Sankyo Corp. v. Nakamura Trading Corp.*, No. 04-1337, 2005 WL 602596 (6th Cir. Mar. 15, 2005) (unpublished), and *Societe de Conditionnement en Aluminium v. Hunter Engineering Co.*, 655 F.2d 938 (9th Cir. 1981), in support of its claim of a circuit split. Pet. 24-25; *see also* Pet. Ap.. 62a-63a (Dyk, J., dissenting). But these decisions are perfectly consistent with the decision below.

Contrary to the suggestion in the petition, *Sallen* did not "expressly reject[] the proposition that Article III requires a party seeking a declaration of his right to use the defendant's trademark in its internet domain name to demonstrate a reasonable likelihood that it will be sued for trademark infringement." Pet. 24. *Sallen* merely held that there was no need to apply the reasonable apprehension standard in a case where "the dispute had already progressed far *beyond* those cases in which a declaratory defendant only questionably threatened suit." 273 F.3d at 26 (emphasis added). In particular, in *Sallen*, the holder of a disputed internet domain name and the party holding a trademark allegedly infringed by it under a "cybersquatting" law had already litigated aspects of the dispute before a panel of the World Intellectual Property Organization. *See id.* That tribunal had ruled on the merits, and the panel had ordered the domain name transferred to the trademark holder. Under such circumstances, the First Circuit merely held that there was no need to speculate about potential future litigation, because the controversy was already "certain." *Id.* This holding in

no way conflicts with the application of the reasonable apprehension standard in situations where there has been no actual litigation; to the contrary, the First Circuit's discussion presupposes that this is the correct standard in such situations.

Sankyo Corp. is similarly consistent with the decision below. The panel in *Sankyo Corp.* found no justiciable case or controversy in a declaratory judgment action filed to determine the proper forum for as-yet unfiled legal claims available to the declaratory-judgment defendant. In doing so, if anything, the *Sankyo* panel authorized an even more stringent requirement for a case or controversy in the context of issues relating solely to the proper forum for resolving a dispute, because it found that the declaratory-judgment defendant "ha[d] threatened litigation against" the plaintiff, yet still found no case or controversy in light of the fact that the "declaratory judgment action [wa]s merely directed at resolving the forum for NTC's potential claims, which NTC may or may not pursue." 2005 WL 602596, at *4.

Societe de Conditionnement en Aluminium is likewise completely consistent with the decision below. *Societe de Conditionnement en Aluminium* relied upon an express threat of legal action by the declaratory-judgment defendant to support a finding that it was reasonable for the plaintiff "to feel apprehensive about possible patent infringement." 655 F.2d at 945. The Ninth Circuit adopted the "real and reasonable apprehension" standard used by the Federal Circuit below, *id.* at 944, expressly disclaimed any "need to decide exactly what evidence of a real and reasonable apprehension is required in all cases to meet the case or controversy standard," *id.*, and held that the actual manufacture of the allegedly infringing product coupled with an express threat of a lawsuit by the defendant satisfied that standard in the case at hand, *id.* at 945. The panel distinguished between the apprehension of suit and the apprehension of liability, indicating that the latter is required,

but did so not to indicate any weakened standard to support a case or controversy, but rather to clarify that a court need not engage in an inquiry to determine whether, as a matter of fact, an agent of the declaratory-judgment defendant who had threatened a lawsuit had the power to make litigation decisions for that entity. *See id.*

Finally, in a footnote, the petition erroneously relies on three additional cases in asserting a conflict among the federal courts on the question presented. Pet. 25 n.18 (citing *Starter Corp. v. Converse, Inc.*, 84 F.3d 592 (2d Cir. 1996) (per curiam), *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990), and *Dewey & Almy Chemical Co. v. American Anode, Inc.*, 137 F.2d 68 (3d Cir. 1943)). All three of these cases applied the same "reasonable apprehension" standard as that used by the Federal Circuit below, and found that standard satisfied in light of express threats of litigation by the declaratory-judgment defendants. Teva apparently cites these cases because they occasionally use a slightly different verbal formulation of the test, referring to an apprehension of "liability" rather than an apprehension of suit. *See Starter Corp.*, 84 F.3d at 595; *Hal Roach Studios, Inc.*, 896 F.2d at 1555; *cf. Dewey & Almy Chem. Co.*, 137 F.2d at 71. Yet the analysis in each case makes clear that this slight verbal variance has no analytical significance. Indeed, in *Hal Roach*, the panel on the very next page restates the standard as whether the plaintiff "had a 'real and reasonable apprehension' that it would be the subject of an infringement action if it continued with its use of the" products in question. 896 F.2d at 1556. There is simply no judicial conflict that would merit this Court's review.

III. THE PETITION IS WRONG ON THE MERITS OF THE QUESTION PRESENTED.

Finally, the decision below is correct on the merits. The petition is wrong in suggesting to the contrary; and the errors

in its arguments further show why certiorari review is inappropriate in this case.

1. The Federal Circuit correctly ruled that there is no present case or controversy between the parties that would support Teva's declaratory-judgment action. In order for a constitutionally cognizable claim or controversy to exist, there must be an actual dispute between the parties that is both "immedia[te] and real[]." *Md. Cas. Co.*, 312 U.S. at 273. In this case, Teva concedes the facts showing that there is no current dispute between the parties regarding the subject of its declaratory-judgment action, namely the validity or infringement of the '699 patent. Significantly, no conceivable controversy over the '699 patent can occur for some substantial time into the future, in light of Teva's paragraph III certification with respect to the '518 patent — which Teva acknowledges precludes it from obtaining approval for, or marketing, its generic product until after June 2006 without regard to the '699 patent — and Ivax's statutory exclusivity period following it. Teva has not represented that it will ever attempt to market a generic ANDA product, let alone that Pfizer will choose to assert any patent claims against it based upon such a product. Indeed, Teva concedes that Pfizer declined to bring any infringement action of its own in response to Teva's ANDA filing; and Teva itself alleges that Pfizer will not commence such an infringement action, if any, until at least after Ivax's exclusivity period has run. These are precisely the circumstances constituting hypothetical future controversies that this Court has rejected as inadequate to support a justiciable declaratory-judgment action. *See, e.g., id.*

As Judge Dyk indicated in his dissent below, Pet. App. 64a, there is no case or controversy where the declaratory-judgment defendant has expressed no desire to enforce the right in question. *See Textron Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aero., & Agric. Implement Workers of Am.*, 523 U.S. 653, 661 (1998)

(finding no case or controversy where there was "no indication that Textron had any interest in defending the binding nature of the contract" whose validity was the subject of the declaratory-judgment action). Here, Teva itself claims that, far from having any desire to assert its patent rights against Teva, Pfizer has a "financial incentive" *not* to assert those rights, at least until some future time when Teva may lawfully enter the market. Pet. 19. But, as Judge Dyk also recognized, Pet. App. 64a, it is complete speculation whether Teva will ever choose to market its product; and it is even more speculative whether, if Teva did, Pfizer would at that point commence any infringement action. Therefore, under this Court's cases, there is no present controversy over the subject of Teva's action.

The hypothetical character of this lawsuit is underscored by the intervening facts, which show that it is unlikely ever to ripen into an actual dispute. As shown above, Teva and Ivax have now announced that Teva will acquire Ivax, and upon consummation of that transaction, Teva will have no incentive to pursue any application for a generic product to compete with that of its own Ivax subsidiary. This factual development, which also makes it unlikely that Teva will ever choose to proceed with this declaratory-judgment action in the future even if allowed to do so, proves that the Federal Circuit was correct in its prescient conclusion that the parties' "adverse interests have not ripened into an actual controversy." Pet. App. 21a.

2. No doubt in light of these facts, the petition does not primarily argue that there is any present dispute over the infringement or validity of the '699 patent. Instead, Teva alleges that it has sustained an injury from the (pre-Medicare Amendments) statutory scheme governing the ANDA process. Its alleged injury has nothing to do with a fear of suit by, or liability to, Pfizer, but rather rests on the claim that Teva "cannot trigger IVAX's exclusivity" without obtaining a declaration of non-infringement or invalidity,

and therefore that it might be "delay[ed in] in the launch of its generic product until at least six months after the ['518] patent expires." Pet. 23. Similarly, the dissenters below relied upon this same theory of an injury stemming from a delay in FDA approval under the Hatch-Waxman regime. Pet. App. 33a-34a (Mayer, J., dissenting), 55a (Gajarsa, J., dissenting), 65a (Dyk, J., dissenting). Indeed, the Federal Trade Commission, in an *amicus* brief below, acknowledged that the panel's application of the "reasonable apprehension" standard would have been appropriate "in a classic patent declaratory judgment suit," FTC Br. at 17 (internal quotation marks omitted), but urged the Federal Circuit to create a special exception in the Hatch-Waxman context owing to this alleged injury from a delay in being able to obtain FDA approval, *see id.* These arguments are seriously confused and profoundly wrong.

A declaratory-judgment action allows the natural defendant in a dispute to initiate litigation over an injury that would have been the subject of the declaratory-judgment *defendant's* lawsuit that it has not yet initiated, but that is hanging over the head of the declaratory-judgment plaintiff. *See, e.g.*, *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 504 (1959) (holding that the Declaratory Judgment Act "allow[s] prospective defendants to sue to establish their nonliability"). The injury question in a declaratory-judgment action is whether there is a sufficient and immediate harm to the declaratory-judgment *defendant* to support its assertion of a cognizable claim against the declaratory-judgment plaintiff to allow the plaintiff to file an anticipatory action to declare its liability or nonliability for that injury. *See, e.g.*, *Md. Cas. Co.*, 312 U.S. at 273 ("It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case.").

For this reason, Teva's reference to the injury that *it* allegedly suffers from a potential delay in starting Ivax's

exclusivity period under the Hatch-Waxman procedures is ill-conceived. Pfizer is the declaratory-judgment defendant, and Teva is the declaratory-judgment plaintiff. Thus, for purposes of determining whether a declaratory-judgment action about the '699 patent is justiciable, the question is whether *Pfizer* has suffered a legally cognizable injury that is ripe for adjudication, not whether Teva has suffered a legally cognizable injury that is ripe for adjudication. Any such injury to Teva could perhaps conceivably supply standing for it to bring a direct, non-declaratory lawsuit involving proper parties premised on that injury; but it does not make ripe any declaratory-judgment controversy over the '699 patent, which Teva itself alleges that Pfizer has no current interest in asserting against it. Teva's alleged injury would not involve "the same" one as a direct patent-infringement claim brought by Pfizer, and thus cannot support declaratory-judgment jurisdiction. *Md. Cas. Co.*, 312 U.S. at 273.

This conceptual defect is presented particularly starkly in this case. Teva's claimed injury is not only different from the fear of being called to account for Pfizer's claim of patent infringement, but it is the precise opposite of such a claim. Teva's claimed injury results from its claim that Pfizer will *not* assert any patent rights against it for some time if at all, and that Teva will suffer a competitive disadvantage to Ivax as a consequence. Teva thus in effect claims an injury from the very *lack* of any controversy over the '699 patent. Simply to expose the claim is to show why no declaratory-judgment action against Pfizer (as opposed to a lawsuit against Ivax or the FDA) is proper.

It may be assumed, as Teva alleges, that the 180-day exclusivity period for Ivax places Teva at a competitive disadvantage. It may even be assumed, as Judge Dyk assumed (albeit perhaps incorrectly) in dissent, that, under the statute, Teva cannot bring suit directly against either Ivax or the FDA to attempt to eliminate or shorten this competitive disadvantage. The constitutionally appropriate

response to this competitive disadvantage is *not* to treat an unripe, hypothetical claim of infringement by Pfizer as nonetheless justiciable. Rather, as the panel majority recognized, Pet. App. 26a, the constitutionally appropriate response to this situation is to deny justiciability and to allow Congress to amend the statute to address any perceived deficiencies in the legal regime that it created. And that, of course, is precisely what Congress did in the 2003 Medicare Amendments — which is just another reason why certiorari review of the decision below is plainly unwise and unnecessary.

3. Contrary to the claims of the petition, Pet. 14-20, the decision below is also entirely consistent with the intent of Congress in crafting the prospective provisions of the Medicare Amendments, and particularly the provision stating that declaratory-judgment actions may be brought outside the initial 45-day period for the patentee to sue. 35 U.S.C. § 271(e)(5). By its express language, that provision does not attempt to confer any new jurisdiction beyond that already available under the Declaratory Judgment Act, and contemplates that any such jurisdiction must be "consistent with the Constitution," *id.*, including the constitutional requirement that a real, immediate, and ripe case or controversy must exist.

Indeed, Congress left no doubt about whether it expected the "reasonable apprehension" test would survive the amendment. The Conference Committee Report repeatedly states that the drafters "d[id] not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction." H.R. Conf. Rep. No. 108-391, at 836 (2003). *See also id.* (stating expectation that courts would "apply the 'reasonable apprehension test'"); 149 Cong. Rec. S15,567 (daily ed. Nov. 22, 2003) (statement of Sen. Hatch) (noting that "the

settled case law of the 'reasonable apprehension' test remains undisturbed"). The report also observes that "[i]n any given case, . . . a court may or may not find a reasonable apprehension of suit." H.R. Conf. Rep. No. 108-391, at 836.

The petition attempts to dismiss all of this legislative history in a conclusory footnote, Pet. 18 n.12, stating that it "does not reflect the intent of the conferees to apply the reasonable apprehension test" because one of the passages contains the phrase "to the extent required by the Constitution." The footnote ignores the other provisions of the legislative history lacking this qualification, which unquestionably endorse the "reasonable apprehension" standard. In any event, by again referring to the requirements of the Constitution, the legislative history to which the petition refers (like the statutory text) in effect embraces the traditional requirement of a real, immediate, and ripe controversy, including the "reasonable apprehension of suit" test.

Finally, a provision that would have purported to confer automatic jurisdiction such as Teva urges here was proposed in the Senate, but was ultimately rejected. In the Senate bill, a patentee's failure to sue within 45 days of receipt of a paragraph IV notice would have "establish[ed] an actual controversy between the applicant and the patent owner sufficient to confer subject matter jurisdiction in . . . any action . . . for a declaratory judgment that any patent that is the subject of the certification is invalid or not infringed." Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. § 702(c) (2003). The proposal was rejected in conference after Senator Hatch, co-sponsor of the Hatch-Waxman legislation, expressed concern about the constitutionality of authorizing "subject matter jurisdiction for a declaratory judgment based on the failure to bring a suit . . . particularly in light of [the] manner in which the U.S. Courts of Appeals, including the Federal Circuit, have developed and applied the 'reasonable apprehension' test."

149 Cong. Rec. S8691 (daily ed. June 26, 2003) (statement of Sen. Hatch).

In short, through the plain language of the Medicare Amendments, through the express articulation of the conference report, and through a rejection of a more expansive proposal, Congress endorsed the "reasonable apprehension" test and expected the courts to continue to apply it in cases under the amended statute. The petition has no proper basis for suggesting otherwise.

CONCLUSION

The petition for a writ of certiorari should be denied.

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In the Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF APOTEX INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF APOTEX INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER[1]

With the consent of the parties, *amicus curiae* Apotex Inc. respectfully submits this Brief in support of the Petition for a Writ of Certiorari submitted by Teva Pharmaceuticals USA, Inc. ("Teva").[2]

IDENTITY AND INTEREST OF *AMICUS CURIAE*

Amicus curiae Apotex is a generic pharmaceutical company dedicated to bringing lower-priced generic drugs to market. In light of Apotex's familiarity and knowledge of the issues, Apotex's *amicus* brief can aid this Court in reaching a proper decision on Teva's Petition.

More specifically, Apotex, like Petitioner Teva, submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic sertraline hydrochloride product before the expiration of Pfizer Inc.'s U.S. Patent No. 5,248,699 ("the '699 patent"). Teva's Petition involves the same drug product and patent. And like Teva, Apotex initiated a declaratory judgment action against Pfizer. Apotex's suit, like Teva's suit, was dismissed for lack of subject matter jurisdiction. Apotex's appeal is pending before the United States Court of Appeals for the Federal Circuit. Apotex, therefore, has a direct interest in the outcome of this appeal.

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[1] In accordance with Supreme Court Rule 37.6, *amicus curiae* Apotex Inc. states that this Brief was authored in its entirety by the counsel listed on the cover, and no person or entity other than the *amicus* listed on the cover made a monetary contribution to the preparation or submission of this Brief.

[2] Counsel of record for the parties do not object to Apotex Inc.'s filing of this Brief. In accordance with Supreme Court Rule 37.2(a), Apotex is submitting the written consent provided by the parties for filing contemporaneously herewith.

Apotex also has a significant interest in this Court granting Teva's Petition because the Federal Circuit's decision impermissibly departs from this Court's precedent. The Federal Circuit concluded that the circuit's so-called "reasonable apprehension" test—which the Federal Circuit previously considered to be only a prudential rule—is a Constitutional requirement. In reaching this conclusion, the Federal Circuit ignored fundamental and controlling precedent from this Court.

Moreover, the Federal Circuit's ruling improperly eviscerates the plain language of the relevant statute, as well as Congress' express intent. In 2003, Congress enacted new statutory provisions designed for the explicit purpose of allowing ANDA applicants to initiate declaratory judgment actions with respect to a specific category of patents. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"). The ruling under review here effectively eliminates those provisions. In so doing, the Federal Circuit's decision misapplies other precedent of this Court.

The Federal Circuit's decision, if allowed to stand, will have far-reaching negative consequences for generic pharmaceutical manufacturers, the generic pharmaceutical industry as a whole, and the public that relies upon generic companies like Apotex and Teva to bring more affordable drugs to market. It is, therefore, imperative that this Court grant Teva's Petition.

SUMMARY OF ARGUMENT

Apotex submits this *amicus* brief in support of Teva's petition for a *writ of certiorari*. The Federal Circuit's decision will delay generic competition, thus significantly harming the generic industry and the American public. The decision below severely undermines an ANDA applicant's ability to learn, before commercialization of its generic drug, whether it will be subject to patent infringement liability.

This decision cannot stand for at least two fundamental reasons. First, the Federal Circuit's decision runs afoul of controlling precedent from this Court by elevating the circuit's prudential jurisdictional rule (the "reasonable apprehension" requirement) to an Article III Constitutional requirement. Second, the decision effectively nullifies crucial provisions of the MMA—provisions that Congress designed to prevent delays in generic competition by authorizing ANDA applicants to bring declaratory judgment actions on patents that the brand companies identify as claiming the drug or a method of using the drug for which the ANDA applicant seeks approval. Only by granting Teva's Petition can this Court correct these errors and effectuate Congress' express goal of getting "generic drugs into the hands of patients at reasonable prices--fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

ARGUMENT

I. The Federal Circuit's Decision Elevates The "Reasonable Apprehension" Test To A Constitutional Standard, In Direct Contravention Of This Court's Precedent.

The Federal Circuit reached the astonishing conclusion that its "reasonable apprehension of suit test represents . . . a constitutional requirement." *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1335 (Fed. Cir. 2005), *reh'g denied*, 405 F.3d 990 (Fed. Cir. 2005), (App. 19a.)[3] This holding runs contrary to decades of controlling precedent from this Court.

This Court previously, and repeatedly, has held, the *only* Constitutional limitation on the exercise of subject matter jurisdiction is the actual "case or controversy" requirement of Article III. Indeed, it is well-established under this Court's controlling precedent that the only

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[3] References to "App. ___" are to the Appendix attached to Teva's Petition for a Writ of Certiorari.

prerequisite to jurisdiction under the Declaratory Judgment Act is an "actual controversy" under Article III, which merely requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 167 (1997); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239-40 (1937); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993).

Nothing in this Court's prior rulings requires a declaratory judgment plaintiff to satisfy the Federal Circuit's two-part reasonable apprehension test before an "actual controversy" will be found to exist. In fact, the Federal Circuit itself recognized at one point that an actual controversy under Article III could exist outside or regardless of any reasonable apprehension of suit. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997); (*see also* App. 28a-29a (Mayer, J., dissenting)). Thus, contrary to the Federal Circuit's ruling below, so long as a "case or controversy" exists, it is legally irrelevant whether the applicant faced a "reasonable apprehension" of suit by the patentee. (*See* H.R. CONF. REP. NO. 108-391, at 836 (2003) (stating that a declaratory judgment plaintiff need only show a reasonable apprehension "to the extent [such a showing is] required by the Constitution"), App. 82a-83a).

Accordingly, the Federal Circuit's ruling below cannot stand. The "reasonable apprehension" test is not an Article III Constitutional requirement. Only this Court's review can rectify the Federal Circuit's improper rewriting of Article III of the U.S. Constitution.

II. The Federal Circuit's Decision Runs Afoul Of This Court's Precedent By Ignoring The Plain Language Of The MMA And Undermining The Intent Of Congress.

The Federal Circuit compounded its Constitutional error by concluding that Congress did not "alter the present

test for determining whether an actual controversy exists in the Hatch-Waxman setting" when enacting the 2003 MMA provisions. (App. 21a.) By effectively eviscerating the plain language of the statute and the explicit intent of Congress, this ruling contravenes additional controlling precedent from this Court.

A. The plain language of the MMA only requires a "case or controversy" under Article III.

In the MMA, Congress specifically authorized ANDA applicants to bring declaratory judgment actions on a certain category of patents, so-called "Orange Book-listed patents." *See* MMA § 1101(a)(2)(C) (codified at 21 U.S.C. § 355(j)(5)(C)), (App. 67a-70a).[4] Congress also instructed that federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any such action . . . ." 35 U.S.C. § 271(e)(5). This statutory language is clear and unambiguous on its face. And this Court has held that "[t]he preeminent canon of statutory interpretation requires [courts] to 'presume that [the] legislature says in a statute what it means and means in a statute what it says there.'" *Bedroc Ltd. v. United States*, 124 S. Ct. 1587, 1593 (2004) (citation omitted); *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (same); *see also Stone v. INS*, 514 U.S. 386, 397 (Fed. Cir. 1995) (recognizing that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect" (citation omitted)).

[4] Under the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, brand-name companies must identify for FDA any patent that claims the drug or a method of using the drug at issue, and for which "a claim of patent infringement could reasonably be asserted" against the maker of a generic equivalent. 21 U.S.C. § 355(b)(1), (c)(2). FDA publishes that patent information in its "Orange Book." Hence, the term "Orange Book-listed patent."

The Federal Circuit did not adhere to this precedent.

Congress declared that the federal courts must exercise jurisdiction to the maximum extent permitted by the Constitution, which, as explained above, only is limited by Article III's "case or controversy" requirement. By requiring a declaratory judgment plaintiff to satisfy the circuit's "reasonable apprehension" test, the Federal Circuit read the plain language out of the statute. In so doing, the Federal Circuit impermissibly failed to follow this Court's prior rulings. *See Bedroc*, 124 S. Ct. at 1593; *Conn. Nat'l Bank*, 503 U.S. at 253-54.

The Federal Circuit attempted to justify its departure from the plain language of the statute by selectively quoting the MMA's legislative history. This, too, rules afoul of prior rulings from this Court. Simply put, the courts cannot use legislative history to alter or rewrite the plain language of a statute. *See Bank One Chicago, N.A. v. Midwest Bank & Trust Co.*, 516 U.S. 264, 279 (1996) ("The law *is* what the law *says*, and we should content ourselves with reading it rather than psychoanalyzing those who enacted it." (Scalia, J., concurring) (citation omitted)); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 386 n.2 (1992) (holding that the "legislative history need not confirm the details of changes in the law effected by statutory language before [the Court] will interpret that language according to its natural meaning." (citation omitted)).

Here, irrespective of anything in the legislative history, the natural and plain meaning of § 271(e)(5) is clear: Jurisdiction is *not* limited to those cases involving a reasonable apprehension of suit, but rather extends to the limits of Article III. If that irreducible Constitutional minimum is satisfied, the issue of reasonable apprehension is irrelevant. Review is necessary, therefore, to remedy the Federal Circuit's misapplication of this Court's precedent.

Finally, the Federal Circuit misconstrued the legislative history upon which it relied so heavily. Congress

enacted the MMA's declaratory judgment provision to ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." (H.R. CONF. REP. NO. 108-391, at 836, App. 82a-83a). As discussed below, the Federal Circuit's ruling has the perverse effect of allowing brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs. To effectuate that Congressional intent here, and to prevent judicial nullification of the MMA's declaratory judgment provision, it is critical for this Court to review the Federal Circuit's decision to confirm that the reasonable apprehension test is *not* coextensive with the "case or controversy" requirement of Article III, as the Federal Circuit held.

B. The Federal Circuit's decision permits brand companies like Pfizer to manipulate the statutory scheme to their benefit.

Rather than carrying out Congress' goal of ending brand company abuse of the generic approval system, the Federal Circuit's decision allows brand companies to continue manipulating Hatch-Waxman to serve their purposes.

1. Congress recognized that early resolution of patent disputes is key to expediting generic market entry.

Before the 1984 Hatch-Waxman Amendments, any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984) ("*Bolar* decision"). As a result, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to the FDA. And because such testing can, and

often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension. *See generally* Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 153-54, 160-61, 165 (1989); Jonathan L. Mezrich, *The Patentability and Patent Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & HEALTH 111, 115-16 (1991/1992).

Hatch-Waxman included a series of statutory provisions designed to speed generic market entry by eliminating the *de facto* patent extension. Congress did away with the *Bolar* decision, exempting the manufacture and/or use of patent-protected drugs from the conventional law on patent infringement, when done for the purpose of preparing an ANDA. *See* 35 U.S.C. § 271(e)(1). This exemption allows the generic company to prepare its ANDA *before* patent expiry, thus furthering Congress' goal of getting generic drug products on the market quickly.

Congress also created a mechanism for litigating patent disputes while the FDA substantively reviews an ANDA. Specifically, Congress required brand companies to submit the number of any patent that "claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(c)(2) *see also id.* § 355(b)(1). The FDA publishes this patent information in the Orange Book. 21 U.S.C. § 355(b)(1), (c)(2), (j)(7)(A); 21 C.F.R. § 314.53(e).

Congress then provided that filing an ANDA seeking FDA approval to market a drug prior to the expiration of a

patent listed in the Orange Book constitutes a statutory act of patent infringement. *See* 35 U.S.C. § 271(e)(2). With this statutory scheme, Congress "create[d] case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (citation omitted); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("Quite obviously, the purpose of subsection[] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]."); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (stating that filing an application seeking FDA approval prior to patent expiration is an "act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity"); *In re '639 Patent Litig.*, No. 97-12416-RCL, 1999 WL 528806, at *1 n.1 (D. Mass. June 15, 1999) (recognizing that Congress "create[d] a case or controversy sufficient to satisfy Article III so that the federal court may exercise its jurisdiction to quickly resolve any disputes concerning a patent claim's validity, enforceability, and/or infringement").

Congress did not design Hatch-Waxman as one-sided legislation in favor of generic drug companies. In the legislation, formally titled the Drug Price Competition and Patent Term Restoration Act of 1984, Congress struck a carefully-crafted balance between protecting legitimate patent rights (thus encouraging innovation) and promoting early generic market entry (thus saving the public money). To that end, the legislation included several provisions designed to benefit brand companies. For example, Congress extended the life of certain pharmaceutical patents (*see* 35 U.S.C. § 156) and included provisions that prevent FDA from approving a generic drug application for 30 months in cases where the patentee commences a patent infringement suit within 45 days after receiving notice of the

generic applicant's desire to seek FDA approval prior to patent expiration (*see* 21 U.S.C. § 355(j)(5)(B)(iii)).

Despite Congress' intent, brand companies found ways to manipulate the system, thereby unduly delaying generic competition and market entry. One delay tactic involved brand companies obtaining and listing patents, but refusing to bring suit when confronted with a generic applicant seeking immediate approval. While perhaps seeming counterintuitive, brand companies found that delaying suit could, in fact, delay generic market entry. This case presents a classic example of such a situation.

Here, Pfizer would have derived no benefit from triggering the 30-month stay of FDA approval of Teva's ANDA by filing suit against Teva on the '699 patent because the other listed patent, U.S. Patent No. 4,356,518 ("the '518 patent"), prevented Teva from going to market until 2006, which is more than 30 months from the date that Teva filed its ANDA in 2002. Specifically, had Pfizer brought suit on the '699 patent immediately, it merely would have given Teva a chance to prove that the '699 patent was invalid or not infringed before the expiration of the '518 patent and, thus, the chance to market immediately upon expiration of the '518 patent. On the other hand, prolonging Teva's uncertainty with respect to its liability under the '699 patent promised to delay Teva's market entry until after the expiration of the '518 patent.

The reason Teva would delay launch is a matter of simple economics. Infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs, such as Zoloft®, would ruin most generic companies. As a result, few generic companies can risk going to market before a final judicial resolution of its patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows these companies to continue selling drugs at monopoly prices while generic companies struggle

to obtain the certainty that they need to launch free from fear of patent infringement liability. This is not speculation on Apotex's part. Indeed, the negative impact that such tactics have on the generic industry and the public readily can be observed by considering the current situation surrounding the drug Accupril®, another Pfizer product.

As in the present case, Pfizer did not sue all ANDA applicants that sought to market a generic product before expiration of Pfizer's Orange Book-listed patents for Accupril®. Fearing that Pfizer would delay suit until they commercially marketed their drugs, ANDA applicants, like Apotex and Mutual Pharmaceutical Company, filed declaratory judgment actions against Pfizer in an attempt to obtain a decision that would allow them to launch without incurring infringement liability. But just as it did here, Pfizer moved to dismiss those declaratory judgment actions for lack of subject matter jurisdiction, arguing that Apotex and Mutual could not reasonably fear suit where Pfizer had not sued any subsequent ANDA applicants. After the dismissal of those suits, and just as Apotex and Mutual feared, Pfizer sued the first company (Ranbaxy Pharmaceuticals) to begin commercial marketing of a competing generic drug. (*Pfizer Inc. v. Ranbaxy Pharms. USA, Inc., et. al*, No. 05-620 (D.N.J.)). Pfizer obtained a preliminary injunction requiring Ranbaxy to pull its lower-priced generic Accupril® product from the market, thereby depriving the public of this product. And while several other companies have FDA approval to begin marketing their own generic Accupril® products,[5] they have not done so. Thus, brand companies like Pfizer have, in effect, created a new "*de facto*" exclusivity period in direct contravention of Congress' express intent.

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[5] *See* FDA's list of finally-approved quinapril ANDAs at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=QUINAPRIL%20HCL.

2. Congress enacts the MMA to prevent brand manipulation and to expedite generic market entry.

Faced with staggering increases in the cost of prescription drugs, and concerned about patentee manipulation, Congress enhanced the Declaratory Judgment provisions by enacting the MMA. The declaratory judgment provisions of the MMA are, in fact, a critical component of Congress' new legislative scheme because they are the only effective way to get generic drugs into the hands of patients fast in circumstances where delay better serves the economic interests of a patentee than immediate commencement of an infringement action. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1072-73 (D.C. Cir. 1998).

The Federal Circuit's decision entirely undermines Congress' attempt to prevent further gaming of the system by brand companies, such as Pfizer. Indeed, Pfizer's transparent "gaming" of the system here, and with Accupril®, is precisely the "sad and saddening" situation that Congress designed the Declaratory Judgment Act and MMA to remedy. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988); (App. 35a (recognizing that "[s]ubsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.") (Mayer, J. dissenting)).

By running afoul of Congressional intent, the Federal Circuit's decision also runs contrary to other precedent from this Court. *See Miller v. French*, 530 U.S. 327, 328 (2000) (citing *Sinclair Ref. Co. v. Atkinson*, 370 U.S. 195, 215 (1962) for proposition that "where, as here, Congress has made its intent clear, this Court must give effect to that

intent"); *Flora v. United States*, 357 U.S. 63, 65 (1958) (stating that "[i]n matters of statutory construction the duty of this Court is to give effect to the intent of Congress, and in doing so our first reference is of course to the literal meaning of words employed").

This Court should hear Teva's Petition in order to reverse the Federal Circuit's ruling, which, without question, runs contrary to Congress' intent when enacting both Hatch-Waxman and the 2003 MMA declaratory judgment provisions. Absent review by this Court, both the generic pharmaceutical industry and the American public will suffer.

CONCLUSION

For all these reasons, the Court should *grant* Teva's Petition.

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No. 05-48

IN THE
SUPREME COURT OF THE UNITED STATES

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AARP AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST[1/]

AARP is a nonprofit, nonpartisan membership organization of more than 35.5 million persons aged 50 and

[1/] No counsel for any party authored any portion of this brief. No persons other than *amicus curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consent and non-opposition of the parties have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

older, dedicated to addressing the needs and interests of older Americans. AARP works to ensure that everyone has access to needed health care and prescription drugs, but prescription drug treatments are particularly important to older persons who have the highest rate of prescription drug use. Persons over 65, although only 13 percent of the population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000) *available at* http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726.

Prescription drug spending has skyrocketed over the last decade and a half. Since 1990, national health expenditures on prescription drugs has quadrupled -from $40.3 billion to $179.2 billion in 2003. Centers for Medicare and Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Select Calender Years 1980-2003 *at* http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp. The rising costs of prescription drugs have left many older Americans unable to afford necessary medications.[2/] Access to generic drugs can help ameliorate the harm done by the high costs of prescription drugs, sparking AARP efforts at the state and national level to increase access to lower cost generic versions of drugs. AARP has filed *amicus curiae* briefs in prescription drug litigation related to access to

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[2/] Research shows that patients' response to the higher drugs costs is to reduce consumption. Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000); Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings From A 2003 Survey* Health Affairs (Web Exclusive) 157-58 (Apr. 19, 2004) (12.8% of all adults report not getting prescription drugs because of cost.)

generics in several Circuits, including the case below in the Federal Circuit, *Teva Pharmaceuticals, Inc. v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005). AARP also filed an amicus in the recent case of *Merck KgaA v. Integra Lifesciences I, Ltd.*, _U.S._, 125 S. Ct. 2372 (2005)(involving patent infringement exception). AARP strongly supported inclusion of § 1101(a)(C), § 1101(b)(2)(D) and §1101(d) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355(j)(5)(C) with respect to abbreviated new drug applications, 21 U.S.C. § 355(c)(3)(D) with respect to new drug applications, and 35 U.S.C. § 271(e)(5) with respect to subject matter jurisdiction over patent disputes). Those provisions, among others designed to allow non-infringing drugs to come to market sooner, expressly permit a "civil action to obtain patent certainty" in the form of a declaratory judgement action when the patent holder or name brand manufacturer declines to initiate a patent infringement action. 21 U.S.C. § 355(c)(3)(D), (j)(5)(C).

AARP has a great interest in the Courts' jurisdiction over the question of whether the sale of generic versions of popular and expensive drugs would infringe a valid patent.[3/] It is in all consumers' interest to assure that patent disputes will be resolved expeditiously so that if there is no patent infringement, generic alternatives to brand name drugs will be available as soon as possible. For these reasons, AARP files this brief supporting Petitioner's request for certiorari.

[3/] With sales of $3.3 billion in 2003, Zoloft is one of the best selling drugs in the world. Pfizer, 2003 Financial Report at 7 *available at* http://www.pfizer.com/are/investors_reports/annual_2003/financial2003.pdf.

REASONS FOR GRANTING THE PETITION

A. The Federal Circuit's Decision Thwarts Congress' Intention to Stop Drug Companies from Exploiting Aspects of the Hatch-Waxman Act To Delay Generic Competition.

Title XI – "Access to Affordable Pharmaceuticals" of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (MMA) is the first Congressional effort in many years to reign in a pattern of laws which have extended intellectual property protection to branded drugs, and which have delayed entry of affordable generic drugs:

> Over the past two decades, Congress has enacted a series of laws that have greatly increased the "effective patent life" enjoyed by brand name prescription drugs . . . . Considered individually, each of these laws offers a reasonable approach to stimulate pharmaceutical innovation and ensure broad access to new medications. Viewed collectively, the laws have conferred multiple and additive protection on prescription drugs.

Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, NIHCM Issue Brief at 1 (Aug. 2000) *available at* http://www.nihcm.org/prescription.pdf. The "average effective patent life of many new drugs has increased by at least 50 percent between the early 1980s and today." *Id.* "Lengthening patent terms and providing other forms of [intellectual property protection] to branded drugs delay the entry of generic drugs, which are usually far less expensive." *Id.* at 3.

Congress began to recognize that drug companies were using provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act) in ways never intended, which resulted in delaying consumers' access to affordable medications.[4/] The Hatch-Waxman Amendments aimed to strike a careful balance of encouraging innovation by brand name manufacturers while still fostering generic competition in order to control escalating drug expenditures. But some companies gamed the law in ways which actually stifled competition. Congress' answer to restore the balance was to pass Title XI – "Access to Affordable Pharmaceuticals" of the MMA.

First, in § 1101, Congress limited the stay of generic competition granted to name brand manufacturers when generic manufacturers filed Abbreviated New Drug Applications (ANDAs) with the FDA. It was limited to a single 30 month period following the instigation of litigation to determine patent validity, thereby "allowing lower-priced generic products to enter the market more quickly." Joint Explanatory Text to the MMA Conference Agreement, H.R. Conf. Rep. No. 108-391, at 836 (2003) *reprinted in* 2004 U.S.C.C.A.N. 2187. This was to prohibit the successive stacking of 30 month stays which some patent holders utilized to delay approval of generic versions of "several blockbuster drugs and cost consumers billions of dollars."

[4/] *See* Testimony of Timothy J. Muris, Chairman Federal Trade Commission, before the United States Senate Committee on the Judiciary, *The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace* (June 17, 2003) (presenting the findings of its report, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002)); David Gross, AARP Public Policy Institute, *Generic Drugs*, AARP Issue Brief at 15 (2003) *available at* http://research.aarp.org/health/ib61_generic.html.

149 Cong. Rec. S15882-03 at S15884 (Nov. 25, 2003) (remarks of Sen. Kennedy during consideration of the Conference Report on the MMA).

Second, in § 1102, Congress restructured the 180-day exclusivity period granted to a generic company when it was the first to file an ANDA challenging a patent (known as paragraph IV certification) and it established that its product did not infringe. Congress now requires the generic company to forfeit exclusivity if it does not begin producing the product within 75 days of an event resolving the patent dispute, either through settlement, court decision or dismissal. This eliminated the incentive under the old law for name-brand and generic manufacturers to "park" the exclusivity period granted to first-to-apply generics through an agreement not to market the generic thereby blocking all other generic companies from coming to the market. 149 Cong. Rec. S15670-03 at S15746 (Nov. 24, 2003)(remarks of Sen. Schumer during consideration of the Conference Report for the MMA).

Third, in § 1101(a)(C) of Title XI, Congress clarified that generic manufacturers could bring a declaratory judgment action to "seek a prompt resolution of . . . patent issues" where the patent holder has not initiated a patent infringement action within 45 days after receiving notice of a patent challenge. 149 Cong. Rec. S15882-03 at S15884-5 (Nov. 25, 2003)(remarks of Sen. Kennedy during consideration of the Conference Report for the MMA). This is an essential provision because it is the legal proceedings surrounding resolution of the patent issues which trigger all of the other threshold events under the Federal Food, Drug and Cosmetic Act that determines when and whether a generic can come to market. Leaving the initiation of such proceedings solely to the discretion of the patent holder

allows the patent holder to control when competition could commence, and to defer commencement as long as possible.

B. Congress Intended That Courts Should Exercise their Declaratory Judgment Jurisdiction to the Limits of their Article III Power.

The language, structure, and history of § 1101(a)(C) reveal Congress' intent that courts favor declaratory judgment jurisdiction to promptly resolve patent issues that might delay generic competitors to brand name drugs. While general declaratory judgment authority for federal courts was already authorized under 28 U.S.C. § 2201 to resolve "a case of actual controversy," § 1101(a)(C) of the MMA expressly provides for "a civil action to obtain patent certainty" where the patent owner or brand name manufacturer has not brought suit within 45 days of the generics' challenge to the patent. Section 1101(a)(C)(i), "Declaratory Judgment Absent Infringement" corrects an imbalance created by Hatch-Waxman provisions which allowed the brand name drug company to extend patent life and control competition by controlling the timing of infringement/invalidity disputes. Section 1101(d) provides that "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction . . . [over] a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5). The new provisions simply make clear what the old law implied: that courts should resolve patent disputes whether or not the patent holder has initiated suit. The Joint Explanatory Text to the Conference Agreement on the law explains that:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation

> between generic drug manufacturers and pioneer drug companies. . . .The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. . . .

H.R. Conf. Rep. No. 108-391, at 836 (2003). Congress made explicit that the courts should exercise their authority to resolve patent disputes to the limit of their Article III power specifically recognizing that an ANDA has been filed with a paragraph iv certification and that the patentee has not filed an infringement suit -- the very circumstances of this case -- in determining jurisdiction. *Id.*[5/] As Senator Kennedy recognized, the "clarification of a generic applicants right to bring a declaratory judgment action is crucial to ensuring prompt resolution of patent issues, which is essential to achieve our goal of speeding generic drugs to market." 149 Cong. Rec. S15882-03 at S15885 (Nov. 25, 2003).

As of August 1, 2005, generic drug manufactures have 303 pending ANDAs containing paragraph IV patent certifications, certifying that their generic version will not infringe a brand name manufacturer's listed patent or that such patent is invalid.[6/] While we do not know the factual background on each of these patent disputes and the various incentives the patent holder has to promptly bring suit or not, we do know well enough that this scenario results in concrete

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[5/] Section § 1101(d), codified at 35 U.S.C. § 271(e)(5). The constitutional authority of the federal courts to decide declaratory judgment actions where there has been a paragraph IV ANDA certification was discussed extensively in the Congressional Record. 149 Cong. Rec. S15751-55 (Nov. 24, 2003).

[6/] U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Paragraph IV Patent Certifications As of August 1, 2005 *at* www.fda.gov/cder/ogd/ppiv.htm.

controversies where an affirmative remedy is needed. *See, In re Cardizem CD Antitrust Litigation,* 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm. Inc.,* 344 F.3d 1294 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F.3d 740 (E.D. N.Y. 2001). The sooner the invalidity or non-infringement can be conclusively established for any of these drugs, the sooner consumers benefit from lower cost generics. But if a court does not resolve the issue of patent validity because the patent holder does not initiate suit, it effectively blocks generic entry.[7/]

In this case, there has been an assertion by the patent holder that it intends to exclude all those who would seek to copy its product, made in the form of a representation to the government by its listing its patent in the FDA's Orange book.[8/] There is a challenge to the legitimacy of those patent

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[7/] *See* 149 Cong. Rec. S15885-86 (Nov. 25, 2003)(Sens. McCain, Schumer and Kennedy discussing courts exercising jurisdiction over declaratory judgments actions involving paragraph IV ANDA certifications and introducing letter from the Federal Trade Commission to Sen. Hatch stating "[w]ithout the right to seek a declaratory judgment, a subsequent generic applicant that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because the subsequent generic applicant will not be sued for patent infringement by the brand-name company.")

[8/] *See* 21 U.S.C. § 355(b)(1) (requiring that a new drug applicant "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which *a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.*")(emphasis added). *See also Minnesota Mining and Mfg. v. Barr Labs.*, 289 F.3d 775, 791(Fed. Cir. 2002)(Gajarsa, J. concurring in the judgment) (stating a declaratory judgment suit is available for ANDA filers not sued by the NDA patentee within the 45-day period and "[t]he two acts of (1) a patentee listing a patent in the

claims made by a would-be competitor, who has prepared to come to market, made in the form of a certification to the FDA that the generic does not infringe the listed patent. The parties' legal positions are in conflict; both businesses have taken steps averring that the other has no right to do what it seeks to do. Despite this, the Federal Circuit found there was no actual controversy because Teva does not have a reasonable apprehension that Pfizer will bring suit imminently if Teva attempts to market the generic. *Teva Pharmaceuticals, Inc. v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005.

As the following discussion makes clear, where generic competition is likely to result in the brand name drug losing substantial market share, the economics of the situation compels the conclusion that Teva not only has a reasonable apprehension of suit, but that it has every basis to believe that Pfizer will bring a patent infringement action at a time designed to protect its lucrative product as long as possible. If the drug patent existed in a vacuum, the court's decision below might make some sense. However, under the legal framework of drug approval, and the realities of the pharmaceutical industry's profitability and pricing structure, there is more than a theoretical question before the court.

C. Pharmaceutical Economics Demonstrate Why Congress Sought to Encourage the Exercise of Declaratory Judgment Jurisdiction.

Legislation was badly needed: "[a]s the Federal Trade Commission has shown, however, in recent years both

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Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of non-infringement.")

brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition." 149 Cong. Rec. S15882-03 at S15884 (Nov. 25, 2003) (remarks of Sen. Kennedy during consideration of the Conference Report on the MMA). According to IMS Health (a large pharmaceutical market research firm), the generic drug share of the total number of prescriptions rose steadily from 18.6 % in 1984 to 42.4 % in 1996, but declined in 1998 to 41.3 %. Michie I. Hunt, BlueCross BlueShield Association, *Prescription Drug Costs: Federal Regulation of the Industry* 51 (2000)[Hunt (BlueCross)]. Generic drugs' market share as a percentage of total dollar sales slipped from a high of 12.2% in 1995 to 8.6% in 1998. *Id.* The significance of the decline in generic penetration is a loss for consumers because the greatest price reduction for a particular drug only comes with competition among multiple generic competitors. The more generic versions of the same drug that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the drug product.[9/] Studies of pricing and market share of innovator drugs and their generic counterparts confirm that substantial savings to the consumer occur as soon as the generic is substituted for the brand name

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[9/] David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risk*, 55 Food & Drug L.J. 321, 325-6; *see also* Keith B. Leffler & Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case: An Argument for Per Se Condemnation of Payments by the Patent Holder*, ABA Economics Committee Newsletter 35 (Spring 2002); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Chapter 3 (July 1998) *available at* http://www.cbo.gov/showdoc.cfm?Index=655&sequence=0 [CBO]; Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PharmacoEconomics 110, 115 (1996); Hunt (BlueCross), *supra*, at 61.

drug, and that even more savings occur over time as other generic versions of the drug enter the market.[10/] Because of this, the name brand manufacturer has a strong incentive to limit the number of generic competitors by forestalling any challenge to its patent monopoly. The fewer the competitors, the less the cost differential, and therefore, the name brand keeps a greater market share. But if courts decline to exercise jurisdiction where name brand manufacturers delay resolution of patent disputes, Congresses' intent to balance the playing field between name brand and generic drug manufactures in order to bring down escalating prescription drug costs will be frustrated.

CONCLUSION

The decision over the justiciability over prescription drug patent disputes is a public policy matter impacting many people's health and welfare because it directly affects the cost of pharmaceuticals. AARP urges the Court to grant the petition for a writ of certiorari because this important question of federal law should be settled by this Court.

[10/] Bureau of Competition & of Policy Planning, Federal Trade Commission, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications* 4-5 (Nov. 4, 1999) *available at* http://www.ftc.gov/be/v990016.htm; CBO, "Competition Among Generic Drugs"; Grabowski, *supra*, at 115; *see also In re Cardizem CD*, 200 F.R.D. 326, 327-8 (E.D. Mich. 2001).

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BRIEF *AMICUS CURIAE* OF THE GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Generic Pharmaceutical Association ("GPhA") represents over 120 companies that manufacture more than ninety percent of all affordable prescriptions dispensed in the United States each year, accounting for more than one billion prescriptions annually. GPhA accordingly has a significant interest in the proper construction of the so-called Hatch-Waxman scheme, which Congress enacted to speed the marketing of generic drugs while protecting the legitimate patent rights of brand-name drug companies.

STATEMENT OF THE CASE

I. Background to the Statutory Scheme

In the 1984 Hatch-Waxman Amendments to the federal patent and drug laws, Congress sought to ameliorate two substantial obstacles to the efforts of generic pharmaceutical manufacturers to compete against brand manufacturers. First, Congress created a streamlined process for FDA approval of generic drug products through which generic manufacturers may submit an Abbreviated New Drug Application (ANDA) demonstrating the bioequivalence of the so-called "pioneer" product and its generic equivalent. 21 U.S.C. 355(j)(2)(A).

Second, Congress adopted a scheme to expedite the litigation of patent disputes. Generic manufacturers, which seek to compete with a brand product already in the marketplace, often face the prospect of a patent infringement suit by the brand company. Such a suit, if successful, could result in debilitating liability if the generic drug were marketed but later found to infringe the patent. Thus, as Congress well knew, in cases of genuine doubt, generic manufacturers may decline to

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[1] Pursuant to S. Ct. R. 37.6, *amicus* states that no counsel to a party authored this brief in whole or in part and that no person other than *amicus curiae* and its members made a financial contribution towards the preparation and submission of the brief. Letters reflecting the consent of the parties have been lodged with the Court.

launch their less-expensive products, even if the brand company's patent claims would ultimately have been rejected.

Congress accordingly created a statutory mechanism to permit early resolution of potential patent infringement claims against a new generic drug prior to its marketing. Under Hatch-Waxman, brand manufacturers must identify any patent for which "a claim of patent infringement could reasonably be asserted" against the maker of a generic equivalent. 21 U.S.C. 355(b)(1), (c)(2). FDA publishes that patent information in its "Orange Book." In turn, a generic manufacturer's submission of an ANDA challenging the validity, enforceability, or infringement of an Orange Book-listed patent constitutes a statutory act of patent infringement, vesting the federal courts with subject matter jurisdiction over an infringement suit. 35 U.S.C. 271(e)(2).

Congress contemplated that these provisions would resolve patent disputes soon after the ANDA is filed. To encourage generic companies to avail themselves of these new statutory provisions, Congress amended the statutory scheme in other ways as well. For example, Congress created an incentive for brand companies to bring a patent infringement claim promptly after learning of the ANDA filing. If a brand company initiates patent litigation within forty-five days of receiving notice of an ANDA applicant's challenge to its patent, FDA must defer approval of the generic product for thirty months. 21 U.S.C. 355(j)(5)(B)(iii).

Congress also encouraged generic drug development by providing that the owner of the first ANDA containing a challenge to a listed patent receives a 180-day period of marketing exclusivity against other generic competitors. 21 U.S.C. 355(j)(5)(B)(iv). Specifically, the FDA must defer approval of later-filed applications until 180 days after the earlier of two specified dates. *Ibid.* Particularly relevant here, a later generic applicant can trigger the start of this 180-day period by obtaining a judgment declaring the listed patent invalid, unenforceable, or not infringed. *Ibid.*

The Hatch-Waxman provisions were only a partial success, however. Through various tactics, brand manufacturers could use the exclusivity period granted to first ANDA filers to block later generic competitors out of the marketplace for years. Despite the thirty-month stay that would result if a brand company initiated suit within the forty-five-day Hatch-Waxman window, brand companies often had a substantial incentive to refrain from instituting litigation before the generic drug was brought to market. A judicial determination could backfire by producing a finding of non-infringement that would trigger the start of the 180-day exclusivity period, thereby allowing more generic companies to enter the market sooner. Moreover, declining to institute patent litigation could leave in place a cloud of patent uncertainty that delayed generic market entry longer than a patent suit itself.

District courts have often ruled that declaratory judgment actions must be dismissed for failure to satisfy the Federal Circuit's "reasonable apprehension" test. Even though Congress clearly contemplated that generic manufacturers would be permitted to resolve patent claims through a declaratory judgment suit against the patentee, the Federal Circuit, which has exclusive jurisdiction over patent appeals, has held that a declaratory judgment suit was impermissible unless the plaintiff itself faced a reasonable apprehension of suit from the patentee. *E.g.*, *BP Chems.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (1993). That rule rested on that court's "pragmatic" concern that merely obtaining a patent should not subject the patentee to litigation. *Ibid.*

In response to these continuing impediments, Congress enacted further legislation in 2003 "to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." Conf. Rep. No. 108-391, at 836 (2003). As amended, the legislation provides that, if the brand manufacturer does not bring suit within the forty-five-day Hatch-Waxman period, the generic competitor may itself institute a declaratory judgment action. 21 U.S.C. 355(j)(5)(C). Recognizing its power to remove the Federal

Circuit's prudential standing barrier, Congress further provided that the district courts would have jurisdiction over such a suit to the fullest "extent consistent with the Constitution." 35 U.S.C. 271(e)(5).

II. The Instant Litigation And The Lower Court Rulings

1. This case arises from petitioner Teva's intention to market a generic equivalent to respondent Pfizer's antidepressant Zoloft® (the trade name for the drug sertraline). As is relevant here, Pfizer listed in the Orange Book two patents that it claimed could reasonably be asserted against a competitor to Zoloft®. According to Pfizer, one expires in 2006; the other (known as the "'699 patent") expires in 2010.

In 2002, Teva filed an ANDA for a generic equivalent to Zoloft®. The ANDA stated that Teva intended to begin marketing as soon as Pfizer's first patent expired in 2006. Teva maintained that the '699 patent either would not be infringed or was invalid.

Teva's ANDA submission constituted a statutory act of infringement of the '699 patent. Pfizer did not, however, sue Teva. Pfizer knew that its refusal to bring suit would impede and delay competition from Teva in two ways. First, it would leave a cloud of patent uncertainty, threatening Teva with the prospect of massive patent liability if it brought its drug to market before the '699 patent expired in 2010.

Second, by avoiding a resolution of the patent dispute, Pfizer prevented FDA from approving Teva's product until at least 180 days *after* Pfizer's first patent expired in 2006. This distinct, categorical approval prohibition arose from a side agreement between Pfizer and another generic manufacturer, Ivax, which had filed the first ANDA for sertraline and thus had a right to generic exclusivity for its sertraline product. Pfizer had sued Ivax for patent infringement in response to the latter's ANDA, but then settled in exchange for a share of the revenues from Ivax's sales. Teva could avoid or limit this additional 180-day delay, however, if it secured a court judgment that Pfizer's '699 patent was either invalid or not in-

fringed prior to the expiration of Pfizer's first patent. See 21 U.S.C. 355(j)(5)(B)(iii).

2. To remove the cloud of patent uncertainty over its product, and to avoid the delay in FDA approval occasioned by the Ivax application and agreement with Pfizer, Teva brought this declaratory judgment action against Pfizer. The district court, however, deemed itself bound to hold that Teva's claim was not ripe because Teva itself faced no imminent suit from Pfizer. Pet. App. 37a-47a. The district court notably did not dispute that Pfizer was refusing to sue precisely to limit generic competition. Instead, it concluded that this fact ironically deprived Teva of standing, for "Pfizer's self-interest in" deferring the resolution of the patent dispute only "makes the prospects of [it bringing] a lawsuit against Teva (or anyone else) even more remote." *Id.* 46a.

3. Teva appealed, supported by the Federal Trade Commission as *amicus curiae*.[2] The FTC emphasized the "important role" this case would play "in furthering competitive pharmaceutical markets and in lowering health care cost[s]." FTC Panel Br. 3. "The issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment" may be "the *only* means by which a generic drug maker may be able to" bring a competing product to market. *Ibid.* (emphasis added). The FTC explained: "If the district court's decision is upheld, it will enable first generic applicants and brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug." *Id.* 3-4 (emphasis in original).

A divided panel of the Federal Circuit nonetheless affirmed. Pet. App. 1a-36a. The panel majority acknowledged this Court's prior holding that the existence of an "actual con-

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[2] The FTC's brief (FTC Panel Br.) is available at http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf.

troversy" sufficient to bring a declaratory judgment action depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Pet. App. 12a (quoting *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

Teva's brief demonstrated that there is indeed a concrete controversy between it and Pfizer. For example, by listing its patents in the Orange Book, Pfizer had declared that Zoloft® was protected by the '699 patent, whereas Teva contends that the '699 patent did not preclude its market entry. Pfizer had moreover previously invoked that very patent to sue Ivax when it sought to introduce a generic equivalent for Zoloft®. Notwithstanding that Teva's ability to bring its product to market was directly precluded by Pfizer's conduct, Pfizer had refused Teva's request for a covenant not to sue.

Despite these undisputed facts, the Federal Circuit concluded that its so-called "reasonable apprehension" test is a constitutional threshold for bringing a declaratory judgment action. Pet. App. 20a. The court held that a declaratory judgment action is justiciable only if there is "an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." *Id.* 13a. Indeed, the plaintiff must "demonstrate that it has a reasonable apprehension of *imminent* suit." *Id.* 16a.

The panel majority concluded that Teva could not meet this rigorous standard because the very point of Teva's claim is that Pfizer seeks to *avoid* a court adjudication of the dispute: "Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringment or invalidity determination * * *." Pet. App. 16a. The majority found it irrelevant that Teva was injured by this state of affairs:

> The fact that Teva is disadvantaged from a business standpoint * * * and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

Id. 26a (emphasis added). It continued:

> [I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage * * *. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

Ibid.

4. Teva petitioned for rehearing en banc, again supported by the FTC as *amicus curiae*.[3] The petition was denied over the dissenting votes of three judges who issued two dissenting opinions. See Pet. App. 48a.

REASONS FOR GRANTING THE WRIT

The petition for certiorari should be granted for several reasons. The court of appeals' decision is flatly contrary to this Court's precedents identifying the "case or controversy"

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[3] The FTC's brief (FTC En Banc Br.) is available at http://www.ftc.gov/ogc/briefs/050208teva.pdf.

required to invoke the jurisdiction of the federal courts. The ruling below moreover conflicts with decisions of other circuits that faithfully apply this Court's decisions. The question is also of indisputable importance. This Court has in the past granted certiorari to review important rulings of the Federal Circuit on questions of patent law, and it should do so here.[4]

This case also is an ideal vehicle to resolve the question presented. Teva's claim against Pfizer presents two distinct injuries that, in *amicus*'s submission, give rise to an Article III case or controversy. Teva is both (a) precluded from securing FDA approval, and (b) deterred from entering the market as a consequence of the prospect of patent liability. By granting the petition, the Court can efficiently address in one case whether either or both injuries are sufficient to trigger the jurisdiction of the federal courts.

Finally, it is important to recognize that the number of opportunities for this Court to resolve the question presented will diminish rapidly if certiorari is denied. The Federal Circuit's ruling precludes generic drug manufacturers from instituting litigation in the circumstances presented in this case. If this Court were to deny certiorari in this case, other similarly situated generic manufacturers would be hard-pressed to incur the costs of instituting new suits, appeal to the Federal Circuit, and petition for certiorari based merely on the prospect that in a later case the Court would reverse course and grant review.

Certiorari accordingly should be granted. At the least, the Court should invite the Solicitor General to file a brief expressing the views of the United States.

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[4] For recent examples, see, *e.g.*, *Merck KGaA* v. *Integra Lifesciences I*, 125 S. Ct. 2372 (2005), *vacating and remanding* 331 F.3d 860 (2003); *Holmes Group* v. *Vornado Air Cir. Sys.*, 535 U.S. 826 (2002), *vacating and remanding* 13 Fed. Appx. 961 (2001); *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), *vacating and remanding* 234 F.3d 558 (2000).

I. The Decision Below Is Contrary To This Court's Precedents Defining The "Case Or Controversy" Required By Article III Of The U.S. Constitution And Conflicts With The Precedent Of Other Circuits.

Congress has granted the federal courts jurisdiction to decide declaratory judgment suits brought by generic drug manufacturers against brand manufacturers to resolve patent claims to the fullest "extent consistent with the Constitution." 35 U.S.C. 271(e)(5). The Federal Circuit held that the Constitution prohibits such a suit unless the generic manufacturer "has a reasonable apprehension of [an] *imminent* suit" by the brand manufacturer. Pet. App. 16a (emphasis in original).

That ruling cannot be reconciled with this Court's precedents. "The irreducible constitutional minimum of standing,'" this Court has held, "contains three requirements":

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact" – a harm suffered by the plaintiff that is "concrete" and "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability – a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. *Citizens for a Better Env't*, 523 U.S. 83, 103 (1988) (citations omitted).

The court of appeals held that Teva failed to meet the first standing requirement because the only injury it was willing to recognize – a suit by Pfizer – was insufficiently "imminent." That holding is clearly wrong. This Court's precedents require that the *injury* be "imminent," as opposed to "conjectural" or "hypothetical." There is no requirement that *litigation* filed by the other side must be imminent. Put another way, Article III provides for jurisdiction not merely when there is a "case" but also when there is a "controversy." That requirement is satisfied in these circumstances.

The Federal Circuit's contrary holding is flatly at odds with this Court's decision in *Cardinal Chemical Co.* v. *Morton International*, 508 U.S. 83 (1993), addressing the circumstances in which Article III permits a declaratory judgment action with respect to a patent infringement claim. Recognizing that "a party seeking a declaratory judgment has the burden of establishing the existence of an actual controversy," this Court explained that "[i]n patent litigation, a party may satisfy that burden, and seek a declaratory judgment, even if the patentee has not filed an infringement action." *Id.* at 95. In support, it quoted with approval Judge Markey's recognition in *Arrowhead Industrial Water* v. *Ecolochem*, 846 F.2d 731, 734-35 (CAFC 1988), that cases such as this present

> the sad and saddening scenario that led to enactment of the Declaratory Judgment Act * * * . In the patent version of that scenario, a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword. * * * Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the *patent owner refused to grasp the nettle and sue*. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests. *The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual "controversy" required by the Act.*

Cardinal Chem., 508 U.S. at 95-96 (emphasis added). Accord 10B Charles Alan Wright et al., FEDERAL PRACTICE & PROCEDURE § 2751 (3d ed. 1988).

As this case demonstrates, the Federal Circuit refuses to heed *Cardinal Chemical*. Instead, it insists that a declaratory judgment plaintiff have not only a real and immediate contro-

versy with the defendant, but also the prospect of an imminent suit.

Outside the patent context, this Court's seminal ruling "upholding the [declaratory judgment] statute" involved, as Judge Dyk explained in his opinion dissenting from the denial of rehearing en banc, a situation precisely analogous to the one here – "one in which there was no imminent risk of suit because the potential plaintiff declined to sue." Pet. App. 61a. In *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227 (1937), the plaintiff insurance company sought a declaration of its obligations to the policyholders. Not only had the policyholders "not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability," *id.* at 239, but Aetna sued for the very reason that there was no present prospect of the parties' rights being adjudicated. This Court nonetheless found a sufficient controversy because the case involved a "definite and concrete dispute" relating to the parties' "legal rights and obligations." *Id.* at 242. "Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages." *Id.* at 240-41.

Prior to the transfer of exclusive jurisdiction of such questions to the Federal Circuit, the regional circuits faithfully applied this Court's precedents in analogous circumstances.[5] The Eighth and District of Columbia Circuits con-

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[5] This Court's practice of reviewing Federal Circuit decisions when "other courts have held or assumed" the contrary, *Pfaff* v. *Wells Electronics*, 525 U.S. 55, 60 (1998), recognizes that conflicts between the Federal Circuit's decisions and those of other circuits on "patent issues" are "useful in identifying questions that merit this Court's attention," *Holmes Group* v. *Vornado Air Circulation Sys.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring).

sidered not whether the plaintiff has a reasonable apprehension of an imminent suit, but instead whether the plaintiff had a reasonable apprehension that it will face either an infringement suit or *the threat of one.* See, *e.g.*, *United Christian Scientists* v. *Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152, 1158 (CADC 1987); *Sherwood Medical Indus., Inc.* v. *Deknatel, Inc.*, 512 F.2d 724, 727-28 (CA8 1975). That standard is met here, as Teva unquestionably faced a reasonable threat of suit given that Pfizer listed the '699 patent in the Orange Book, refused to provide Teva with a covenant not to sue, and sued Ivax for patent infringement.[6]

Two other circuits similarly applied a less stringent standard than the Federal Circuit's. The Ninth Circuit enquires whether "the plaintiff has a real and reasonable apprehension that he will be subject to liability" – a fact-based determination that looks at "[t]he acts of the defendant * * * in view of their likely impact on competition and the risks imposed upon the plaintiff, to determine if the threat perceived by the plaintiff [is] real and reasonable." *Chesebrough-Pond's, Inc.* v. *Faberge, Inc.*, 666 F.2d 393, 396 (1982). And while the First Circuit – which considered the question in the context of a dispute over which it had jurisdiction under World Trade Organization procedures – expressly holds that the "reasonable

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[6] In reviewing the totality of the circumstances to determine whether such a reasonable apprehension exists, the Eighth and District of Columbia Circuits have accorded weight to the fact that the patentee has previously brought infringement actions, just as Pfizer previously sued Ivax. See *Sherwood Medical*, 512 F.2d at 728 (although past infringement action, standing alone, not dispositive, patentee's entire course of conduct, including past action, gave rise to "reasonable apprehension"); *United Christian Scientists*, 829 F.2d at 1159 n.25 (noting that "prior record of infringement charges against the declaratory plaintiff or others similarly situated" is one of the factors "which courts have regularly recognized as buttressing a reasonable apprehension of impending litigation").

apprehension of suit" standard "is not the only way" to establish Article III jurisdiction unless "the only controversy surrounds a potential, future lawsuit," it holds that, even in the absence of such a potential suit, the facts of a particular case may demonstrate that such a controversy exists. See *Sallen* v. *Corinthians*, 273 F.3d 14, 25 (2001).

2. It cannot be seriously argued that Teva's declaratory judgment complaint fails to state an Article III case or controversy under this Court's precedents and the standard articulated by other circuits. There is a concrete legal controversy between Teva and Pfizer with respect to whether Teva's product infringes on Pfizer's patent. Pfizer's listing of the '699 patent in the Orange Book constituted a representation by it that "a claim of patent infringement could reasonably be asserted" against a generic equivalent on the basis of the patent. 21 U.S.C. 355(b)(1), (c)(2). Teva has alleged its intention to market a drug that, according to the Orange Book listing, Pfizer believes will violate its patent. Under the federal patent laws, Teva's filing of an ANDA challenging the validity or infringement of that patent constitutes a statutory act of patent infringement as matter of law. 35 U.S.C. 271(e)(2). Pfizer has further refused Teva's request that it acknowledge that Teva's product is non-infringing. In these circumstances, only a suit by Teva can resolve the controversy.

Nor is there any serious dispute that the current state of affairs greatly harms Teva. Even the Federal Circuit did not doubt in the *slightest* that Teva had suffered an "injury." Pet. App. 26a. Instead, it deemed the fact that "Teva is injured from a business standpoint" and "finds itself at a competitive disadvantage" (*ibid.*) irrelevant as a matter of law.

The legal dispute that Teva seeks to resolve has at least two definite, adverse consequences for Teva that would be remedied by a judgment in its favor – and, indeed, can *only* be remedied by such a judgment. First, Teva is deterred by the prospect of devastating infringement liability from entering the marketplace. Manufacturers in Teva's position frequently

have massive investments tied up in the development of their generic equivalents by the time they submit an ANDA. As Judge Mayer recognized in his dissent, ANDA applicants such as Teva "suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic product free from infringement allegations." Pet. App. 35a. "[D]eclaratory judgment actions serve an important role because the [FTC's] Generic Drug Study showed that *no* generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book." FTC Panel Br. 8 n.9 (emphasis added).

Second, even if Teva wanted to market its drug before adjudicating Pfizer's patent claim, the FDA *cannot* approve Teva's generic equivalent for at least 180 days after the expiration of Pfizer's first patent, unless Teva secures an earlier favorable patent judgment. See *supra* at 2. Thus, "[t]he controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays Teva from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against Teva." FTC En Banc Br. 9. "Absent such a decision, Teva (and every other ANDA applicant) instead must wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that Teva can advance the date of the approval of its product is through this litigation. Absent this action, Teva suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days." FTC Panel Br. 21-22.

3. The Federal Circuit's holding that Teva nonetheless fails to state a justiciable controversy because it does not face an "imminent suit" from Pfizer (Pet. App. 16a) is insupportable. The "pragmatic" concern (*EMC Corp.* v. *Norand Corp.*, 89 F.3d 807, 811-12 (CAFC 1996)) that gave rise to the Federal Circuit's reasonable apprehension test is completely missing here. That requirement was adopted to "protect[]

quiescent patent owners against unwarranted litigation" when they have "done nothing but obtain a patent." *Arrowhead Indus. Water* v. *Ecolochem, Inc.*, 846 F.2d 731, 736 (CAFC 1988). The prudential standing rule thereby seeks "to determine whether the need for judicial attention is real and immediate." *BP Chems.*, 4 F.3d at 978. The rule is "but a pragmatic attempt to give operational guidance against which patentees can structure their conduct, and control their litigation costs, in a fact-specific area of the law." Pet. App. 51a (Gajarsa, J., dissenting). But in this context, "exercising jurisdiction over this action does not force a lawsuit on a 'quiescent' patent-owner." FDA Panel Br. 13. To the contrary, as Judge Mayer recognized in his dissent, "[b]y listing its patent [in the Orange Book], Pfizer has informed the world that the '699 patent precludes anyone from marketing a generic sertraline hydrochloride product until it expires." Pet. App. 32a. Both the district court (*id.* 46a) and the court of appeals (*id.* 16a) recognized that Pfizer – like other brand manufacturers in its position – declined to file suit not because of ambivalence about its patent rights, but instead to prevent generic competition. Any doubt is resolved by the facts that Pfizer sued Ivax on an indistinguishable claim and refused to grant Teva a covenant not to sue.

Thus, the Federal Circuit's odd rule that litigation must be imminent before it may be brought "is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market." FDA Panel Br. 12. The prudential interest in limiting the litigation burdens on patent holders is simply overborne in this circumstance.

In any event, even if it otherwise applied, the Federal Circuit's prudential standing rule did not survive Congress's enactment of a specific directive that the federal courts shall exercise jurisdiction over suits such as Teva to the fullest extent consistent with the Constitution. See 35 U.S.C. 271(e)(5); *Raines* v. *Byrd*, 521 U.S. 811, 820 n.3 (1997) (Congress may eliminate prudential standing rules by statute).

II. The Question Presented Is Vitally Important To Pharmaceutical Competition.

The petition for certiorari should also be granted because it presents a question of fundamental importance to competition in the pharmaceutical industry and, accordingly, to the American public that relies so heavily on lower-priced generic drugs to combat the skyrocketing costs of healthcare.

1. Because the Federal Circuit has exclusive jurisdiction over patent disputes, the ruling below governs every attempt in the nation by generic pharmaceutical companies to resolve patent disputes with brand manufacturers. The decision below provides a roadmap for brand manufacturers to preclude litigation of all such disputes. "No incumbent will ever make the threat [of litigation], if it can simply ride out the term in the listed patent." Pet. App. 57a (Gajarsa, J., dissenting).

As this Court has previously recognized Congress enacted the statutory provisions of the Hatch-Waxman scheme at issue here "to enable new drugs to be marketed more cheaply and quickly." *Eli Lilly & Co.* v. *Medtronic*, 496 U.S. 661, 676 (1990). "Quite obviously, the purpose of [these provisions] is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." *Id.* at 678. And just as "[t]he scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement" (*ibid.*), so too it "will not work" if the patent holder can prevent generic manufacturers from establishing in court that there has been no patent infringement.

The FTC concurs that "[d]eclaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime" (FDA Panel Br. 12), helping to "further[] competitive pharmaceutical markets and [lower] health care costs" (FTC En Banc Br. 2). Indeed, it concludes, "even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because

competition among generic manufacturers has a strong impact on the price of a drug." FTC Panel Br. 8.

In the course of preparing this brief, *amicus* GPhA surveyed its membership to determine the significance of the question presented. The responses confirm that the Federal Circuit's decision fundamentally affects competition throughout the pharmaceutical industry. The survey conclusively established two facts: (i) the FTC and the dissenting judges below are correct in their conclusion that these circumstances present a concrete controversy; and (ii) the number of drugs affected by the ruling is large and constantly growing.

GPhA's members report that they regularly defer launching a product until they can litigate the question of patent infringement to at least a district court judgment.[7] By not bringing suit, brand companies perpetuate paralyzing uncertainty that allows them to continue selling their branded drugs

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[7] To cite just a few examples,

- Endo Pharmaceuticals launched its equivalent to Oxycontin® only after a favorable Federal Circuit ruling. *Purdue Pharma L.P.* v. *Endo Pharmaceuticals*, 410 F.3d 690 (2005).
- Eon Labs launched its equivalent to Sporanox® (produced by Johnson & Johnson affiliate Janssen) only after a favorable district court judgment. *Janssen Pharm. N.V.* v. *Eon Labs*, 374 F. Supp. 2d 263 (E.D.N.Y. 2004), aff'd, 134 Fed. Appx. 425 (CAFC 2005).
- Geneva launched its equivalent to Augmentin® only after a favorable district court judgment; other manufacturers then followed suit. *Geneva Pharm.* v. *GlaxoSmithKline*, 213 F. Supp. 2d 597 (E.D. Va. 2002), aff'd, 349 F.3d 1373 (CAFC 2003).
- Barr Labs launched its equivalent to Mircette® only after a favorable district court judgment. *Bio-Technology Gen. Corp.* v. *Duramed Pharms., Inc.*, 174 F. Supp. 2d 229, 232 (D.N.J. 2001), rev'd, 323 F.3d 1356 (CAFC 2003).
- Conversely Eon Labs has been precluded from litigating with respect to its generic equivalent to Pfizer's Accupril® and has not entered the market despite having final approval.

at monopoly prices. The decision below is particularly pernicious because it is the drugs that the public most frequently uses – and hence that give rise to the greatest possible infringement liability – that will suffer reduced competition. Infringement damages for blockbuster drugs such as Zoloft® (which generates revenues for Pfizer well in excess of $2 billion annually) would ruin most generic companies.

GPhA's members also report that the ruling below would have a sweeping effect. Generic manufacturers regularly seek to market generic equivalents and represent in their ANDAs that the patents listed in connection with the innovator drug are either invalid or will not be infringed. The most recent data published by the FDA indicates that generic manufacturers have filed such ANDA certifications for 314 drugs. See http://www.fda.gov/cder/ogd/ppiv.htm (last visited Sept. 7, 2005). More than seventy were submitted in the last two-and-a-half years alone. *Ibid.* Many of those drugs are likely to present patent issues that ought to be resolved promptly but, under the Federal Circuit's ruling, cannot.

These examples illustrate the sweep of the ruling below:

- The ruling below does not merely affect Teva even with respect to Zoloft®. Two other manufacturers filed ANDAs seeking to market generic Zoloft® products and brought similar declaratory judgment actions. Both were dismissed on the same ground as the Federal Circuit's ruling here. *Dr. Reddy's Labs.* v. *Pfizer*, No. 03-726, 2003 U.S. Dist. LEXIS 24,351 (D.N.J. July 8, 2003) (order); *Apotex* v. *Pfizer*, No. 04-CV-02539 (S.D.N.Y. Apr. 1, 2004) (order), appeal pending, No. 05-1199 (CAFC).

- The ruling below affects numerous drugs other than Zoloft®. For example, there are the attempts to litigate the patent validity/non-infringement of generic equivalents to Pfizer's Accupril® (which generates nearly $600 million in annual U.S. sales). Various generic manufacturers have filed ANDAs for Accupril®. When Pfizer failed to file suit, two of those manufacturers sought a declaratory judgment. Their

cases were dismissed, on the same rationale as the ruling below. *Mutual Pharm. Co.* v. *Pfizer*, No. 03-CV-1116, 2004 U.S. Dist. LEXIS 4846 (D.D.C. Mar. 24, 2004); *Apotex* v. *Pfizer*, No. 03-CV-990-SLR, 2004 U.S. Dist. LEXIS 11,930 (D. Del. June 28, 2004).

- Teva and Mylan Laboratories have filed ANDAs with respect to Merck & Co.'s Proscar®. Merck did not file suit against either. Mylan has a pending declaratory judgment action against Merck. *Mylan* v. *Merck & Co.*, No. 05-cv-1416 (SHR) (M.D. Pa.).

- Teva has a pending declaratory judgment with respect to SmithKline Beecham's Famvir®.

2. By substantially impeding generic competition, the Federal Circuit's ruling will directly injure consumers and the public health. Because generic drugs are generally sold for a fraction of the prices of their brand counterparts, the substitution of generic drugs for brand drugs results in billions of dollars in savings each year.[8] A one-percent increase in the substitution of generic drugs for brand drugs could result in a savings of up to $2 billion per year, while the widespread substitution of generic drugs for brand drugs whenever possible could save U.S. consumers as much as $17 billion per year. Dep't of Health and Hum. Servs. Task Force on Drug Importation, REPORT ON PRESCRIPTION DRUG IMPORTATION 68 (Dec. 2004), available at http://www.hhs.gov/importtaskforce/Report1220.pdf (visited Sept. 7, 2005); Steven Findlay, *Easy*

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[8] See FDA, FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs (June 12, 2003), available at http://www.fda.gov/oc/initiatives/generics/whitepaper.html (visited Sept. 7, 2005) (average price of a brand drug is $72, compared with $17 for its generic counterpart); Statement of the FTC on *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements*, Before the Comm. on the Judiciary of the U.S. Senate (May 24, 2001), available at http://www.ftc.gov/os/2001/05/pharmstmy.htm (estimating that consumers saved $8 to $10 billion in 1994 by substituting generics for brand drugs).

Way To Cut Costs Of Drugs: Generics, USA TODAY, May 13, 2004, at 23A.

Access to generic pharmaceuticals is thus "perhaps the single most important route to lower personal and national drug costs during the next decade." Findlay, *supra*. Indeed, the cost savings created by generic pharmaceuticals translates directly into improved public health and, thus, lives saved. As the FDA Commissioner has explained, generic drugs "are an increasingly important way to provide the American people with safe, effective and affordable medical treatment." *Generics: FDA Announces Measures To Improve Generic Drug Access*, DRUG WEEK, Mar. 26, 2004, at 231. See also Nat'l Inst. For Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* 19 (June 2002), available at http://www.nihcm.org/GenericsPrimer.pdf (positing that "[t]he advent of [the generic equivalent of the anti-depressant Prozac]" may help rectify the "persistent under-diagnosis and under-treatment of depression in the U.S.").

The high costs of prescription are a significant – and in some cases, insuperable – barrier to proper treatment for many Americans, particularly the elderly. See *Generics Key To Cost Control*, UPI, May 19, 2005 (quoting Dr. Jan Berger, chief clinical officer of Caremark Rx Inc.: "the No. 1 reason why patients do not take their medicine is because it is too expensive"); AARP, Prescription Drug Costs And The Role Of Generic Drugs 2 (Oct. 1, 2002), available at http://assets.aarp.org/rgcenter/health/rx_generic.pdf ("[N]early one in four Americans 45 and older (24%) reported *not* being able to afford a prescription drug because no generic version was available.") (emphasis in original).

CONCLUSION

The petition for a writ of certiorari should be granted or, at a minimum, the Court should invite the Solicitor General to file a brief expressing the views of the United States.

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IN THE

Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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INTRODUCTION

The Federal Circuit has grafted onto Article III a limitation on the subject matter jurisdiction of federal courts in declaratory judgment actions that this Court has never articulated and that other circuits have rejected. By its ruling, the court of appeals denied jurisdiction throughout the country in a class of cases in which Congress specifically authorized declaratory judgments in order to accelerate the introduction of generic drugs and thereby moderate the explosive growth in expenditures on prescription drugs.

Pfizer's opposition to certiorari ignores this Court's settled Article III jurisprudence, the decisions of other circuits, and the importance of the questions presented for national health care policy. The petition for a writ of certiorari should be granted.

ARGUMENT

I. The Issues Presented for Review Will Continue to Affect Many ANDA Applicants Under the Medicare Amendments.

Pfizer suggests that the enactment of Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (the "Medicare Amendments"), so altered the regulatory scheme of the Hatch-Waxman Act that the questions presented in Teva's petition will not arise in the future. Nothing could be further from the truth. If anything, the Medicare Amendments have increased the stakes.

Before the Medicare Amendments, a judgment of invalidity or noninfringement of an Orange Book patent

triggered the first ANDA filer's 180-day exclusivity period. The Medicare Amendments removed that trigger but replaced it with a provision of arguably greater consequence. Now, if the first ANDA filer does not launch its generic product within 75 days of such a judgment, the first filer forfeits its exclusivity altogether. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), (j)(5)(D)(ii).[1] Pfizer's suggestion that the Medicare Amendments have eliminated the "concern" that led to Teva's declaratory judgment suit is, therefore, simply incorrect. That suggestion is particularly implausible because it leaves unexplained why Congress would specifically provide for a declaratory judgment remedy for generic companies *in the very amendments that, according to Pfizer, eliminated the need for the remedy.*[2]

Moreover, as Congress recognized,[3] there are various circumstances in which the owner of a patent listed in the Orange Book would choose not to commence litigation against a generic company in furtherance of a strategy to delay generic competition. For example, it is very common for companies to list multiple patents in the Orange Book

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1 While only a judgment obtained by a subsequent applicant with "tentative approval" can result in a forfeiture, such approval is commonly given if the drug described in the ANDA is found to satisfy the bioequivalency and other statutory requirements for generic drugs set forth in 21 U.S.C. § 355(j)(2)(A).

2 Indeed, one searches Pfizer's opposition (and the decision below) in vain for any explanation at all why Congress would go to the trouble of amending the Hatch-Waxman Act specifically to authorize declaratory judgment actions if, as Pfizer contends, Congress simply intended to maintain the legal status quo.

3 *See* Pet. at 16-17; Pet. App. at 77a.

with respect to a given drug.[4] A patentee might well sue a generic company on only one patent, obtain the 30 month stay of FDA approval, and hold the other patents in reserve to commence later litigation if the generic company prevails in the first suit. Such a strategy makes sense even with only one ANDA filer. The generic drug company can only obtain "patent certainty," as Congress intended to encourage the prompt introduction of generic drugs, by seeking a declaratory judgment on those other patents. Under the Federal Circuit's decision here, however, if the patentee has taken no steps beyond listing the patents in the Orange Book, the declaratory judgment action is likely to be dismissed.

Further, as the amicus briefs of the Generic Pharmaceutical Association and Apotex, Inc. make clear, the risk of catastrophic damages for launching a generic version of a blockbuster drug such as Pfizer's Zoloft® that generates hundreds of millions of dollars of sales *each month* is more than many generic companies can dare to run. The practical need to obtain patent certainty before launching is compelling, affects many companies, and *continues to exist even after the first ANDA filer's exclusivity period has run.*[5]

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[4] A search of the Orange Book for drugs for which Pfizer holds the NDA shows that Pfizer maintains multiple patent listings for a great many of its drugs. The Orange Book search page is located at http://www.fda.gov/cder/ob/docs/queryah.htm.

[5] Pfizer points to an earlier version of the Medicare Amendments that would have deemed an Orange Book patentee's failure to commence an infringement suit to "establish an actual controversy... sufficient to confer subject matter jurisdiction." Opp. at 27. But Congress rejected this version, not because it sought to preserve the "reasonable apprehension" test, as Pfizer argues, but rather because the Justice Department advised Congress that the attempt to define an "actual controversy" would usurp the power of the courts to determine the scope of Article III. *See* Brief of United States

(*continued next page*)

The issues raised by the petition are not "narrow, fact-based" issues unsuited for certiorari review. While the application of the Federal Circuit's "reasonable apprehension of imminent litigation" test may at times turn on the particular facts, whether that test is, as the Federal Circuit ruled, mandated by Article III is a pure question of law.

Pfizer also contends that Teva's announced agreement to acquire the stock of IVAX diminishes the importance of this case. As the press release that Pfizer cites[6] notes, this transaction is contingent on a number of factors, including regulatory and shareholder approval which have not yet occurred.

II. Teva's Claim for Declaratory Relief Was Ripe.

Pfizer tries to cast the decision below as an application of settled ripeness principles. Neither the Federal Circuit nor Pfizer ever characterized the issue here in ripeness terms or invoked this Court's ripeness cases in support of the denial of subject matter jurisdiction. This is not surprising because, under this Court's ripeness jurisprudence, Teva's claim for declaratory relief was plainly ripe.

The most obvious reason why that is so is that Teva seeks to resolve a patent infringement claim that has already accrued. By statute, Teva's submission of an ANDA with a

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Senators Edward M. Kennedy, John S. McCain, and Charles E. Schumer as *Amici Curiae* in Support of Petition of Teva Pharmaceuticals USA, Inc. for Rehearing *En Banc*, No. 04-1186 (Fed. Cir.). The bill as enacted preserved the proper sphere of judicial authority by creating a cause of action and directing courts to exercise jurisdiction unless it would violate Article III to do so.

[6] http://www.tevapharm.com/pr/2005/pr_536.asp

"Paragraph IV" certification that Pfizer's patent is either invalid or not infringed by Teva's generic formulation constitutes an act of infringement. 35 U.S.C. § 271(e)(2). As this Court has recognized, the purpose of this statute is precisely to create an actual controversy sufficient to support judicial resolution of disputes concerning the application of Orange Book patents to proposed generic drugs. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

Pfizer cannot deny that an infringement claim in response to a generic company's submission of an ANDA with a Paragraph IV certification would be ripe. Pfizer has commenced such actions many times, including one against IVAX on the very patent at issue here. But if Pfizer could have asserted a ripe claim for patent infringement against Teva, then it cannot dispute the ripeness of Teva's declaratory judgment action to resolve the identical claim. "It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the [justiciability] inquiry is the same in either case." *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). If Teva's claim is unripe, then so is the infringement claim authorized by 35 U.S.C. § 271(e)(2), without which, as this Court observed, the Hatch-Waxman Act scheme "will not work." *Eli Lilly*, 496 U.S. at 678.

Moreover, unlike the claims in cases such as *Texas v. United States*, 523 U.S. 296, 300 (1998), Teva's claim does not "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." Teva's submission of an ANDA with a paragraph IV certification constitutes a statutory act of infringing Pfizer's patent. The patent's validity depends on facts antedating its issuance, and resolution of the infringement claim turns on applying the

claims in that patent to a drug product that Teva has already developed, manufactured and described in great detail in its ANDA. There is absolutely nothing contingent or hypothetical about the claim that Teva seeks to resolve. This is not a case in which "the courts would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n, Inc.* v. *Sierra Club*, 523 U. S. 726, 733 (1998).

Nor is Teva seeking to challenge a statute that may never be enforced or whose enforcement is committed to other branches of government. *Cf. Boyle v. Landry*, 401 U.S. 77, 80-81 (1971) (declining to enjoin enforcement of criminal statutes at the behest of individuals who have never even been threatened with prosecution; companion case to *Younger v. Harris*, 401 U.S. 37 (1971)).[7] Congress specifically bestowed sole responsibility on federal courts to hear declaratory judgment actions brought by ANDA applicants under the circumstances presented here.

Finally, under this Court's formulation of the ordinary test for ripeness — which Pfizer does not even mention — there is no question that Teva's declaratory judgment action is ripe. The ripeness inquiry requires courts "to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149

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[7] Pfizer's suggestion that "[t]he Federal Circuit's 'reasonable apprehension' test is a well-established application of the imminent threat of prosecution standard," Opp. at 17, is far wide of the mark. The federalism concerns that underlie cases such as *Boyle* are immaterial here. Nor is there any administrative action with which resolution of Teva's lawsuit will interfere. On the contrary, under the Hatch-Waxman Act, the timing of FDA action depends on judicial resolution of patent disputes.

(1967). The infringement and validity issues raised in Teva's complaint are plainly fit for judicial resolution. There is no further factual development needed to resolve them and there is nothing hypothetical about them. Moreover, there is no question that Teva faces hardship if these issues are not resolved. The court of appeals so held, Pet. App. at 25a-26a, and Pfizer has not disputed the point.

III. The Ruling of the Federal Circuit Conflicts With the Rulings of This Court and Other Circuits.

Pfizer fails to reconcile the Federal Circuit's "reasonable apprehension of imminent litigation" requirement with the decisions of this Court and those of other circuits. For example, Pfizer argues that the declaratory judgment defendants in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 687 (1937), had placed Aetna on notice of an adverse legal position by claiming disability benefits in 1930 and 1931. But the insurance company brought its declaratory judgment action in 1934 and this Court's opinion never suggests that the defendants were on the verge of suing to enforce a legal position staked out several *years* before. This Court found the controversy to be justiciable because the issues were, as they are here, focused and concrete, and a decision on them would conclusively resolve an existing legal dispute.

Pfizer dismisses the decisions of this Court defining Article III's "constitutional minimum" in terms of injury in fact attributable to the defendant's conduct and redressable by the relief requested as involving "standing," and not "ripeness." As demonstrated above, shifting the focus to ripeness does not help Pfizer. Moreover, this Court has distinguished between the constitutional and prudential dimensions of ripeness, and the constitutional core of

ripeness is essentially the same as it is for standing. *See Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 79-81 (1978); *National Treasury Employees Union v. United States*, 101 F.3d 1423, 1427-28 (D.C. Cir. 1996). Where, as here, Congress has specifically directed federal courts to exercise subject matter jurisdiction to the constitutional limit, prudential restrictions on subject matter jurisdiction cannot affect the result.

Pfizer's attempts to explain away the other circuit court decisions that reject the Federal Circuit's "reasonable apprehension of imminent suit" requirement are not persuasive. Pfizer does not dispute that in *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14 (1st Cir. 2001), the court did not require the plaintiff to prove that he faced a reasonable apprehension of suit. *Id.* at 25. Pfizer says that *Sallen* is different because earlier consideration of the parties' trademark dispute by a private body had made the contours of that "controversy" "certain." But the contours of the dispute between Teva and Pfizer are no less certain than they were in *Sallen*: the issue is whether Pfizer's patent is valid and whether Teva's generic sertraline product infringes.

Similarly, Pfizer does not dispute that the Sixth Circuit in *Sankyo Corp. v. Nakamura Trading Corp.*, 2005 U.S. App. LEXIS 4339 (6th Cir. Mar. 15, 2005), held that the reasonable apprehension of litigation test is not constitutionally mandated. Pfizer argues that *Sankyo* applied an even more restrictive test, declining jurisdiction notwithstanding an actual threat of litigation by the defendant. However, the plaintiff in *Sankyo* did not seek to resolve the claim that was the subject of the threat but rather a dispute concerning whether that claim was subject to arbitration. The court understandably declined to resolve *that* dispute before the defendant actually carried through on

its threat. The point of *Sankyo* here is that the court recognized that the correct standard for the justiciability is the injury-traceability-redressability test on which Teva relies, and not the Federal Circuit's "reasonable apprehension of imminent litigation" test.

Finally, Pfizer can read *Societe de Conditionnement en Aluminium v. Hunter Engineering Co.*, 655 F.2d 938 (9th Cir. 1981), as consistent with the Federal Circuit's ruling only by ignoring what the Ninth Circuit actually said. That court recognized the important role that declaratory judgment actions play in giving competitors recourse against "scarecrow" patents by providing an opportunity for competitors to obtain a definitive ruling concerning a patent that the patentee chooses not to jeopardize by bringing an infringement suit. *Id.* at 943. While recognizing that an outright threat of infringement litigation — the court said nothing about *imminent* litigation — was sufficient to establish a justiciable case or controversy, the court went on to "conclude that the Constitution has a much lower threshold than this standard would suggest," namely a "real and reasonable apprehension that [the plaintiff] will be subject to liability." *Id.* at 944. This apprehension of liability standard properly focuses less on whether the defendant has rattled its litigation sabers and more on whether the plaintiff has embarked on a course of conduct that would reasonably expose it to liability if the conduct persists. *Id.* This is inconsistent with a requirement of reasonable apprehension that the defendant will commence infringement litigation imminently.

Pfizer suggests that the apprehension of "liability" instead of "litigation" is only a "slight verbal variance [with] no analytical significance." But the policy of providing recourse against "scarecrow" patents that bring about an

anticompetitive effect by virtue of *not* being asserted in litigation makes the distinction both important and clear. One of the principal purposes of the Declaratory Judgment Act was to allow competitors to obtain "patent certainty" in the face of what an earlier Federal Circuit decision referred to as a "Damoclean threat with a sheathed sword." *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988). Sixteen years later, the Federal Circuit changed its mind, ruling that declaratory relief is unavailable unless the sword is out of the scabbard and that Article III mandates that result. This ruling is inconsistent with the Article III jurisprudence of this Court and of other circuit courts.

CONCLUSION

The petition for a writ of certiorari should be granted.

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